UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SERGEANTS BENEVOLENT ASSOCIATION HEALTH & WELFARE FUND, individually and on behalf of itself and all others similarly situated, Plaintiff, v. ACTAVIS, PLC, and FOREST LABORATORIES, LLC, MERZ PHARMACEUTICALS GMBH & CO., KGAA, AMNEAL PHARMACEUTICALS, LLC, TEVA PHARMACEUTICAL INDUSTRIES, INC., BARR PHARMACEUTICALS, INC., COBALT LABORATORIES, INC., UPSHER-SMITH LABORATORIES, INC., WORCKHARDT LIMITED, WOCKHARDT USA LLC, SUN INDIA PHARMACEUTICALS INDUSTRIES, LTD., DR. REDDY'S LABORATORIES LTD., and DR. REDDY'S LABORATORIES INC., Defendants.	C.A. No. 15-cv-6549 **PUBLIC VERSION**
JM SMITH CORPORATION d/b/a, SMITH DRUG COMPANY, on behalf of itself and all others similarly situated, Plaintiff, v. ACTAVIS, PLC, FOREST LABORATORIES, LLC, MERZ GMBH & CO. KGAA, MERZ PHARMA GMBH & CO. KGAA and MERZ PHARMACEUTICALS GMBH Defendants.	C.A. No. 15-cv-7488

MEMORANDUM IN SUPPORT OF DEFENDANTS FOREST AND MERZ'S MOTION TO DISMISS INDIRECT PURCHASER PLAINTIFFS' CLASS ACTION COMPLAINT AND DIRECT PURCHASER PLAINTIFFS' FIRST AMENDED CLASS ACTION COMPLAINT

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INTRODUCTION

Plaintiffs attempt to piggyback on the now-resolved New York Attorney General ("NYAG") injunctive action concerning Namenda, where the court enjoined Forest Laboratories' proposed withdrawal of its older Namenda product.[1] But Plaintiffs' allegations fail at the basic notice pleading level: Plaintiffs allege that by "removing" the older, twice-daily tablet version of Alzheimer's drug Namenda® ("Namenda IR") prior to entry of a generic version ("Generic Namenda IR"), Forest enacted a "hard switch" or "product hop" that forced the market to convert to Forest's innovative, once-daily Namenda XR® capsules ("Namenda XR").[2] IPP ¶ 126 (Forest removed "Namenda IR from the market prior to generic entry"); DPP ¶ 13 (Forest "effectively removed Namenda IR from the market").

One problem: due to the preliminary injunction, Plaintiffs admit that the hard switch *never happened*. On the contrary, Plaintiffs concede that well before Namenda IR was to be removed from the market, on December 15, 2014, the Southern District of New York enjoined Forest's *plans* and Forest "continue[d]" to make Namenda IR tablets available until thirty days after July 11, 2015 (the date when generic memantine became available). DPP ¶ 186 ("Judge Sweet . . . granted an injunction . . . to ***continue*** to make Namenda IR tablets ***available***.") (emphasis added); IPP ¶ 139 ("injunction requiring Forest . . . to ***continue*** to make Namenda IR tablets ***available*** until thirty days after July 11, 2015.") (emphasis added).

Specifically, the NYAG initiated an investigation in February of 2014 and brought suit on

[1] "Plaintiffs" collectively refers to indirect purchaser plaintiffs Sergeants Benevolent Association Health & Welfare Fund (individually, "IPPs"), and direct purchaser plaintiffs JM Smith Corporation (individually, "DPPs"). Defendant Actavis plc is now known as Allergan plc, a public limited company incorporated in Ireland, and Defendant Forest Laboratories, LLC is an indirect wholly owned subsidiary of Allergan plc (collectively referred to as "Forest").

[2] Complaint, *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, plc.*, No. 15-CV-06549 (S.D.N.Y. Aug. 19, 2015), ECF 1 (hereinafter IPP); Amended Complaint, *J M Smith Corp. v. Actavis, plc*, No. 15-CV-7488 (S.D.N.Y. Oct. 13, 2015), ECF 26 (hereinafter DPP).

September 15, 2014.[3] The NYAG moved for a preliminary injunction in September 2014 to keep Namenda IR on the market, and Forest agreed that it would continue to supply Namenda IR while the motion was pending with the court. *New York ex rel. Schneiderman v. Actavis plc*, 787 F.3d 638, 648 (2d Cir. 2015) ("*Namenda II*"). Forest continued to make Namenda IR available until after Generic Namenda IR entry, pursuant to the December 15, 2015 injunction.

The NYAG recently acknowledged that the injunction "prevented [Forest] from removing Namenda IR from the market, or limiting the distribution of Namenda IR" and "was effective in protecting competition in the relevant market and permitting lower cost generic drugs to enter the market." Exhibit to Stipulation of Dismissal With Prejudice at 2, 3, *New York v. Actavis*, No. 14-cv-07473 (S.D.N.Y. Nov. 30, 2015), ECF 96-1 (hereinafter NYAG Settlement).

Plaintiffs do not—and cannot—allege that Forest failed to comply with the injunction. Undeterred by the admitted lack of any hard switch—with Namenda IR tablets continuing to be available (DPP ¶ 186; IPP ¶ 139)—Plaintiffs nonetheless bring these lawsuits premised on an imagined universe in which Namenda IR *was* removed from the market.

Faced with the undeniable fact that Namenda IR "continue[d]" to be "available" and thus that the "hard switch" never happened, Plaintiffs resort to arguing that the *mere truthful announcement* of Forest's future plans to limit or remove Namenda IR from the market itself somehow constituted removal because it encouraged patients and doctors to switch to the newer, better drug, notwithstanding the continued presence of the older product. DPP ¶¶ 172-173; IPP ¶¶ 125-126. But pharmaceutical marketing to doctors is protected commercial speech under the

[3] *See* Forest Labs. Annual Report (Form 10-K), at 46 (May 30, 2014) ("On February 28, 2014 . . . we received Investigatory Subpoena[] from the New York Attorney General's Office . . . regarding plans to discontinue the sale of Namenda tablets"); NYAG Compl., *New York v. Actavis, plc*, No. 14-CV-7473 (Sept. 15, 2014), ECF 1.

First Amendment. *See Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 2665 (2011); *Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures,* 508 U.S. 49, 56 (1993) (Sherman Act not intended "to invade" First Amendment rights). Plaintiffs offer no legal basis to support such an antitrust theory, and there is none because patient choice was "unimpeded," as NYAG admitted.[4] No one was coerced into buying Namenda XR, because Namenda IR was available at all times, and a flood of generic Namenda IR entered the market upon loss of exclusivity in July 2015, thirty days before the injunction expired. Nor do Plaintiffs offer any plausible allegation that any patient or doctor actually *did* switch due to coercion as Plaintiffs speculate, particularly in light of the injunction. Plaintiffs' product hopping claim therefore lacks a "hop" and must be dismissed.

Lacking any cognizable "product hop" theory, Plaintiffs resort to a backup reverse payment theory not pursued by the NYAG despite the NYAG's lengthy investigation of Namenda. Plaintiffs half-heartedly attempt to allege that Forest paid generic competitors to settle Namenda IR patent litigations to unlawfully delay the entry of generic Namenda IR until July 11, 2015. But the desultory Complaints fail to allege *any reverse payments* from Forest to the generic competitors at all—let alone "large and unjustified" reverse payments that may warrant antitrust scrutiny under the Supreme Court's decision in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013).

Basic notice pleading requires more than speculation that there *might* have been a reverse payment to fall within *Actavis'* reach, and *Actavis* makes clear that early entry settlements are

[4] New York Attorney General Settlement Press Release (Nov. 25, 2015), http://www.ag.ny.gov/press-release/ag-schneiderman-announces-resolution-lawsuit-protected-alzheimer%E2%80%99s-patients ("Because the injunction protected competition and allowed low cost generic drugs to enter the market unimpeded, the Attorney General's office has determined that it is no longer necessary to continue legal action.").

lawful, including compensation for "avoided litigation costs." *Actavis*, 133 S. Ct. at 2236. Plaintiffs' failure to allege "large and unjustified" payments (*id.* at 2237) is not surprising because the settlement agreements themselves (which Plaintiffs have and which are attached to this motion) contain no unlawful reverse payments. Similarly, Plaintiffs' contradictory criticism of provisions that could accelerate generic entry ("Generic Entry Acceleration Clauses") is self-defeating: those clauses allow for *even earlier* generic entry. And even if Plaintiffs had stated a viable reverse payment settlement claim, it would be time-barred, as all of the settlement agreements were entered into and announced publicly more than five years prior to commencement of these actions.

Having failed to allege a product hop or a reverse payment, Plaintiffs try to piece together a claim by bundling independently lawful conduct into an unlawful, overarching "scheme" to monopolize. But Plaintiffs present no plausible allegations of an overarching conspiracy or scheme and no plausible allegation of harm, and they cannot save their Complaints by alleging that zero plus zero equals one. *See Pac. Bell Tel. Co. v. linkLine Commc'ns*, 555 U.S. 438, 457 (2009).

Finally, IPPs' state law claims fail on a number of bases repeatedly recognized by courts. In particular, IPPs assert claims for which no plaintiff has standing—a constitutional requirement—and bring claims that would require this Court to countermand state legislatures.

The Complaints therefore fail to state a claim and must be dismissed.

REGULATORY FRAMEWORK

A drug manufacturer wishing to market a new prescription drug must submit a New Drug Application ("NDA") to the Food and Drug Administration ("FDA") and undergo a long, comprehensive, and costly testing process, after which, if successful, the manufacturer will

receive marketing approval from the FDA. *Actavis*, 133 S. Ct. at 2228. The manufacturer may obtain a period of regulatory exclusivity for its product, and may also protect its innovation through patents, which must be listed in the FDA's "Orange Book." In addition to patent and other regulatory exclusivity, if an innovator pharmaceutical company undertakes pediatric clinical studies for its drug at the FDA's request, the FDA may grant the innovator six additional months of market exclusivity. 21 U.S.C. § 355a. This "pediatric exclusivity" period attaches to both the Orange Book listed patents and other regulatory exclusivity periods covering the drug. 21 U.S.C. § 355a(b)-(c).

Under the Hatch-Waxman Act, a manufacturer seeking to introduce a generic drug must file an abbreviated new drug application ("ANDA") with the FDA. 21 U.S.C. § 355(j). If the manufacturer seeks to market its generic version before expiration of a patent listed in the FDA's Orange Book, it must file a "Paragraph IV Certification" asserting that its proposed product will not infringe the listed patent and/or that the listed patents are invalid. DPP ¶ 40; IPP ¶ 39; 21 U.S.C. § 355(j)(2)(A)(vii)(IV). If a generic competitor files a Paragraph IV Certification, the innovator has 45 days to bring suit for patent infringement, which triggers an automatic 30-month stay of the FDA's final approval of the generic's ANDA, to allow litigation to proceed on the relevant patent. DPP ¶ 40; IPP ¶ 40; 21 U.S.C. § 355(j)(5)(B), (j)(5)(F)(ii).

The Hatch-Waxman Act thus establishes an artificial act of patent infringement—the Paragraph IV Certification—which allows the generic competitor to challenge the innovator's patents well in advance of any sale of its generic product. Although Hatch-Waxman establishes a mechanism to allow patent litigation to proceed in advance of potentially infringing sales, it nowhere requires that all such litigation be pursued to the bitter end. Nor does it prohibit the litigants from settling to allow generic competition earlier than patent expiration and thereby

minimize the risk that all parties face in any litigation. *See generally Actavis*, 133 S. Ct. 2223 (discussing and preserving ability of parties to settle patent litigation).

As an incentive for generic competitors to challenge the patents covering innovator products, the first generic firm to file an ANDA containing a Paragraph IV Certification is eligible for 180 days of generic marketing exclusivity during which the FDA may not approve any later-filed ANDAs with Paragraph IV Certifications. DPP ¶ 42; IPP ¶ 41; 21 U.S.C. § 355(j)(5)(B)(iv). Where multiple generic competitors file their ANDAs on the same first date, they share first-filer exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv). Regardless of when the exclusivity period is triggered, first-filer exclusivity automatically terminates upon expiration of the patent and regulatory exclusivity covering the drug. *See* 21 U.S.C. § 355(j)(5)(B)(iv).

FDA approval of an ANDA does not provide any protection for the ANDA holder from the brand company's patents. A court may enjoin entry—or mandate withdrawal of the product—by the ANDA holder in light of the patent. Accordingly, if the generic company launches prior to a final, non-appealable decision on the patent merits—sometimes referred to as launching "at risk"—it still faces the potential of being found liable for patent infringement and potentially massive damages.

FACTUAL BACKGROUND[5]

Forest's Innovation in Alzheimer's Treatments. Forest has been a leader in Alzheimer's disease treatment and research for more than a decade, offering multiple products used to treat Alzheimer's patients based on memantine,[6] including Namenda IR tablets, Namenda IR oral solution, Namenda XR capsules, and combination product Namzaric™. *See* DPP ¶ 90. Merz

[5] For purposes of this motion to dismiss only, Forest accepts the factual allegations in the complaints as true, but reserves all rights to dispute factual allegations.

[6] Memantine is a N-Methy-D-Aspartate receptor antagonist, which works to prevent the overstimulation of glutamate, an amino acid which can cause toxicity to neurons in the brain.

(Merz Pharma GmbH & Co. KGaA and Merz Pharmaceuticals GmbH)[7] originally discovered memantine and owns U.S. Patent No. 5,061,703 ("'703 patent"), which covers all existing approved uses of Namenda. In 2000, Merz exclusively licensed the '703 patent to Forest in the United States, which gave Forest the right to enforce the patent. *See* DPP ¶¶ 2, 93; IPP ¶ 62. Forest researched, developed, and obtained FDA approval of Namenda IR, the first FDA-approved Alzheimer's treatment based on memantine. Forest introduced Namenda IR tablets in January 2004. *See* DPP ¶¶ 2, 94-97; IPP ¶¶ 63-66. In 2005, Forest introduced an oral solution version of Namenda IR. *See* DPP ¶ 98.

Forest's regulatory and patent exclusivity periods for Namenda IR were originally set to expire with the expiration of the '703 patent on April 11, 2015, but the FDA granted Forest a six-month extension of exclusivity in recognition of Forest's work, at the FDA's request, to study the potential use of memantine to treat pediatric autism. *See* DPP ¶¶ 2, 100-102; IPP ¶ 68. "Forest invested almost $70 million in support of clinical studies for the treatment of pediatric autism." *New York v. Actavis, plc*, 2014 WL 7015198, at *11 (S.D.N.Y. Dec. 11, 2014) ("*Namenda I*"). Forest's exclusivity for Namenda IR thus expired on October 11, 2015. *See id.*

In response to competitors offering once-daily Alzheimer's treatments and other benefits of once-daily dosing, Forest engaged in costly research and development to develop once-daily Namenda XR[8]—which the FDA approved in June 2010 and Forest launched in June 2013. *See*

[7] The DPP Complaint names as defendants the German companies Merz Pharmaceuticals GmbH, Merz GmbH & Co. KGaA, and Merz Pharma GmbH & Co. KGaA (collectively "Merz"); these Merz defendants join Forest's accompanying motion to dismiss the DPP Complaint. The IPP Complaint appears to name a different Merz entity, but IPPs have not effected service on Merz. Accordingly, for now, the motion to dismiss the IPP Complaint is on behalf of only the Forest defendants.

[8] Brief for Appellants at 5, *New York ex rel. Schneiderman v. Actavis plc*, No. 14-4624 (2d Cir. Feb. 20, 2015), ECF 262.

DPP ¶¶ 146,149; IPP ¶¶ 99, 102. According to the FDA-approved label, patients taking twice-daily Namenda IR can transition to once-daily Namenda XR as soon as the next day.[9]

Generic Competitors Challenge the '703 Patent Resulting in Procompetitive ANDA Settlements. Starting in 2007, at least 12 prospective generic competitors filed ANDAs for Generic Namenda IR. DPP ¶¶ 102-03; IPP ¶ 69. Forest brought patent infringement suits against each applicant pursuant to Hatch-Waxman procedures, DPP ¶¶ 7, 104-105; IPP ¶¶ 70-71, and these suits were consolidated into one action in the District of Delaware. *See Forest Labs., Inc. v. Lupin Pharm., Inc.*, No. 08-021-GMS-LPS (consolidated) (D. Del.). On July 2, 2009, the Magistrate issued a Report and Recommendation agreeing with Forest's construction of most disputed terms in the patent. Report & Recommendations Regarding Claim Construction, *Forest Labs., Inc. v. Lupin Pharm.*, No. 08-021-GMS-LPS (D. Del. July 2, 2009), ECF 373.

After the Magistrate issued his report recommending claim constructions unfavorable to the generic defendants, four generic defendants entered into individual settlement agreements resolving their separate cases with Forest.[10] The remaining defendants filed objections to the Magistrate's report, but on September 21, 2009 the district court largely adopted it. Memorandum & Order, *Forest Labs., Inc. v. Lupin Pharm.*, No. 08-021 (D. Del. Sept. 21, 2009), ECF 426. The remaining defendants ultimately entered into individual settlements rather than risking a trial.

These "ANDA Settlements" contain no unlawful reverse payments. Rather, the only form of payment made by Forest pursuant to the ANDA Settlements is reimbursement of certain

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[9] *See* Clinical Pharmacology and Biopharmaceutics Review(s) at 4 (Oct. 21, 2009), http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022525Orig1s000ClinPharmR.pdf. (cited at DPP ¶ 12 n.8).

[10] Pursuant to this Court's order, Defendants produced all ANDA Settlements to DPPs and IPPs on November 23, 2015.

of the generic competitors for a limited portion of their costs and attorneys' fees, expenses Forest would likewise have incurred if it instead went to trial and through appeal. The amounts differ across the ANDA Settlements, but none exceed $[redacted]—substantially less than litigation would have cost.[11] The ANDA Settlements and their key terms were publicized through press releases (DPP ¶ 118 n.23), and Defendants filed their settlement agreements with the Federal Trade Commission and the Assistant Attorney General in accordance with the filing requirement of Section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. P.L. 108-173, 117 Stat. 2066, § 1112 (codified at 21 U.S.C. § 355 (2006)).

The first generic to settle was Amneal Pharmaceuticals LLC ("Amneal"), on September 1, 2009. *See* KO Decl. Ex. 1 § 1.14. As a part of this settlement, Amneal released its claim that the '703 patent was invalid, unenforceable, or not infringed. In exchange, Forest granted Amneal a license to market Generic Namenda IR three months before Forest's exclusivity would end. Amneal could enter even earlier if another generic was able to obtain an earlier entry date—in which case Amneal's launch date would be automatically amended to the later of (1) the earliest date the third party would be permitted to launch, or (2) the final FDA approval date of Amneal's product (the "Generic Entry Acceleration Clause"). *See id*.

Several additional generic competitors then settled: Upsher-Smith Laboratories, Inc. ("Upsher-Smith") on September 8, 2009, Wockhardt Ltd. and Wockhardt USA, LLC ("Wockhardt") on September 10, 2009, Sun Pharmaceutical Industries Ltd. ("Sun") on October 9, 2009, Cobalt Laboratories Inc. on October 15, 2009, Teva Pharmaceutical Industries Ltd. on

[11] *See* Declaration of Kristen O'Shaughnessy ("KO Decl.") Ex. 1 § 2.5 ($[redacted]); KO Decl. Ex. 2 § 2.5 ($[redacted]); KO Decl. Ex. 4 § 2.5 ($[redacted]); KO Decl. Ex. 5 § 2.5 ($[redacted]); KO Decl. Ex. 6 § 2.5 ($[redacted]); KO Decl. Ex. 7 § 2.6 ($[redacted]); KO Decl. Ex. 8 § 2.5 ($[redacted]); KO Decl. Ex. 10 § 2.5 ($[redacted]); KO Decl. Ex. 11 § 2.5 ($[redacted]); KO Decl. Ex. 13 § 2.5 ($[redacted]).

November 3, 2009, Dr. Reddy's Laboratories ("DRL") on November 13, 2009, Lupin Pharmaceuticals, Inc. ("Lupin") on December 11, 2009, Orchid Chemicals & Pharmaceuticals Ltd. ("Orchid") on March 23, 2010, and Mylan Pharmaceuticals Inc. ("Mylan") on July 22, 2010. *See* KO Decl. Exs. 2, 4-8,10-11, 14. As with the Amneal settlement, these settlements granted a license for early entry three months before Forest's exclusivity expired, and contained Generic Entry Acceleration Clauses.

Apotex Inc. ("Apotex") settled on September 8, 2009, with a license to enter when the patent and regulatory exclusivity expired, and with a Generic Entry Acceleration Clause. *See* KO Decl. Ex. 3 § 1.14. Torrent Pharmaceuticals Ltd. ("Torrent") settled on similar terms on December 7, 2009. *See* KO Decl. Ex. 9 § 1.11.

In addition to the ANDA Settlements, Forest also entered into two mutually-beneficial business agreements with two generic manufacturers that are not named as defendants in this litigation. First, on March 23, 2010, Orchid agreed to develop and supply Forest with [redacted] active pharmaceutical ingredient (an ingredient in an antibiotic then in development) for [redacted] years ("Orchid Supply Agreement"). *See* KO Decl. Ex. 12 § 3. Forest agreed to pay Orchid $[redacted] to establish this supply, *if* Orchid could meet certain development milestones enabling Forest to bring a new antibiotic to market. *Id.* at § 6. Forest also agreed to pay a consulting fee in three installments of $[redacted] upon completion of the milestones to reimburse Orchid for its development work, manufacturing, third-party contracting, and supply of finished drug vials. *Id.* Second, on July 21, 2010 Forest and Mylan amended a pre-existing distribution and supply agreement originally entered in 2005 between Forest and Mylan's subsidiary Alphapharm ("Mylan Amendment"). *See* KO Decl. Ex. 15. In the Mylan Amendment, Mylan agreed to expend significant upfront costs in order to take over responsibility for manufacturing the

authorized generic[12] for the drug Lexapro®, and Forest agreed to pay Mylan $[redacted] in consideration of the new costs and manufacturing responsibilities Mylan agreed to undertake. *Id.* at § 6.1. [redacted] *See id.* § 6.2.

Early Generic Namenda IR Entry in July 2015. As expected, generic manufacturers began launching Generic Namenda IR in July 2015. Amneal launched its generic product on July 11, 2015. DRL soon followed on July 12, 2015; Mylan launched its product on July 14, 2015. Lupin, Sun, Wockhardt, and Upsher-Smith have also launched Generic Namenda IR products. Generics continue to launch: Alembic Pharmaceuticals, Unichem Pharmaceuticals and Macleods Pharmaceuticals launched products in October 2015. At present, there are numerous competitors selling Generic Namenda IR. DPP ¶ 118; IPP ¶ 83.

Forest's Announced—But Ultimately Enjoined—Plan to Focus on Namenda XR and Change Distribution of Namenda IR. Consistent with the caregiver, physician and patient acceptance of the benefits of once-daily Namenda XR, and in light of the ease of switching from Namenda IR to Namenda XR, on February 14, 2014, Forest announced plans to discontinue twice-daily Namenda IR tablets and focus on the new and improved Namenda XR. *See* DPP ¶ 87; IPP ¶ 95. In June 2014, Forest had to delay its plans to discontinue Namenda IR due to Namenda XR manufacturing problems and thus issued another press release notifying patients that it would continue to manufacture Namenda IR. *See* DPP ¶¶ 182-183; IPP ¶¶ 135-136. In light of the possibility that a small number of patients arguably might continue to need Namenda IR, on November 5, 2014, Forest announced that it would continue to make Namenda IR available to patients with a medical need for the twice-daily drug through Foundation Care, a full

[12] An authorized generic is a generic product sold pursuant to the innovator's NDA—and may be sold by the brand or a licensed third party generic drug manufacturer. *In re Actos End Payor Antitrust Litig.*, No. 13-CV-9244, 2015 WL 5610752, at *3 (S.D.N.Y. Sept. 22, 2015).

service specialty mail-order pharmacy serving patients nationwide. *See* DPP ¶ 87; IPP ¶ 95. Physicians who believed that Namenda IR was medically necessary for their patients could have completed a short form that accompanied the patient's prescription, and Foundation Care would have filled the prescription and delivered the product to the patient by mail. *See* DPP ¶ 87; IPP ¶ 95. Forest never announced a plan to discontinue or change the distribution of the Namenda IR oral solution. *See* DPP ¶¶ 170, 174; IPP ¶ 123.

2014 NYAG Injunctive Action Stops Forest's Proposed Plans. Before Forest altered distribution of Namenda IR in any way, on September 15, 2014, the NYAG filed a Complaint in the United States District Court for the Southern District of New York seeking an injunction preventing Forest from discontinuing Namenda IR or implementing the agreement with Foundation Care.[13] *See* Am. Compl. ¶ 7, *New York v. Actavis, plc*, No. 14-CV-7473 (S.D.N.Y. Dec. 10, 2014), ECF 70. Soon thereafter, Forest agreed to a standstill of its plans pending the litigation of the injunction. *Namenda II*, 787 F.3d at 648. On December 15, 2014, Judge Robert W. Sweet granted New York State's motion for an injunction and ordered Forest to "continue to make Namenda IR (immediate-release) tablets available on the same terms and conditions applicable since July 21, 2013 (the date Namenda XR entered the market)." Order ¶ 1, *New York v. Actavis, plc*, No. 14-CV-7473 (S.D.N.Y. Dec. 15, 2014), ECF 84. The injunction further mandated that Forest publicize the "continued availability of Namenda IR" to pharmacists, patients, caregivers and health plans. *Id.* at ¶ 2. The injunction expired "thirty days after July 11, 2015 (the date when generic memantine will first be available)." *Id*. at ¶ 4. On May 28, 2015, the Second Circuit affirmed Judge Sweet's decision. *See Namenda II*, 787 F.3d 638.

[13] On February 28, 2014, the NYAG commenced an investigation of Forest, asking for information generally concerning Namenda IR. *See* Forest Labs. Annual Report (Form10-K), at 29 (May 30, 2014). However, as its complaint demonstrates, the NYAG did not raise issue with the Namenda IR settlements, and only sought to enjoin Forest's plan to discontinue Namenda IR.

Forest Resolves NYAG Action in 2015 Settlement. Plaintiffs do not allege that Forest failed to comply with any portion of the court's preliminary injunction. On the contrary, in a recent settlement agreement between the NYAG and Forest, the NYAG expressly recognized Forest's compliance with the injunction, stating: "NYAG is unaware of any violation of the Injunction by Allergan." NYAG Settlement at 3.[14] The NYAG in the settlement recognized that the injunction prevented Forest (and its parent company Allergan) from discontinuing Namenda IR, and ensured patient access in all 50 states:

> [T]he Injunction prevented Allergan from removing Namenda IR from the market, or limiting the distribution of Namenda IR, and during the Injunction term and afterwards Allergan has continued to manufacture and supply Namenda IR, thus permitting patient access at all times to Namenda IR in all 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, and Guam.

Id. at 2. And the NYAG recognized that Allergan informed the public of the injunction in a fashion similar to its earlier announcements:

> [I]n December 2014 Allergan informed the healthcare providers, pharmacists, patients, caregivers, and health plans of the Injunction and the continued availability of Namenda IR in the same or substantially similar manner in which it announced in February 2014 the potential plan to discontinue Namenda IR.

Id. at 3. The NYAG confirmed that Allergan "did not impose a 'medical necessity'" requirement for patients to receive Namenda IR," that "at no time before, during, or after the Injunction was Namenda IR made unavailable by Allergan or otherwise limited in distribution," and that the NYAG "received no reports that any patient was denied access to Namenda IR by Allergan before or during the Injunction period." *Id*. The NYAG confirmed in the Settlement that "the

[14] Courts may take judicial notice of documents in a prior litigation "to the extent that they indicate that certain judicial proceedings occurred and that certain findings and averments were made." *See Jasper v. Sony Music Enter., Inc.*, 378 F. Supp. 2d 334, 339 (S.D.N.Y. 2005); *see also Hayden v. Cnty. of Nassau*, 180 F.3d 42, 54 (2d Cir. 1999) (trial court permissibly referred to a government report in "recit[ing] the factual background of the case").

Injunction was effective in protecting competition in the relevant market and permitting lower cost generic drugs to enter the market." *Id.* at 3. After recognizing the effectiveness of the injunction, New York released any and all claims for "any state entity which purchases, reimburses, insures, or is in any way a direct or indirect purchaser of the drug Namenda IR, Namenda XR [or] Namzaric," settling instead for a minimal payment of $171,946 for costs incurred in connection with the investigation and prosecution. *Id*. at 5.

Procedural History—First Wave of Class Complaints Voluntarily Withdrawn. On May 29, 2015, direct purchaser Burlington Drug Company, Inc. filed a complaint in this Court that was substantially similar to the current actions, which was voluntarily dismissed on June 12, 2015. Notice of Voluntary Dismissal, *Burlington Drug Co., Inc. v. Actavis plc*, No. 15-CV-4152 (S.D.N.Y. June 12, 2015), ECF 4. On June 8, 2015, indirect purchaser A.F. of L. also filed a complaint in this Court that was substantially similar to the current actions. Compl., *A.F. of L. v. Actavis plc*, No. 15-CV-4406 (S.D.N.Y. June 8, 2015). Defendants provided A.F. of L. with the ANDA Settlements between Forest and the named generic defendants, and on September 2, 2015, shortly after reviewing the ANDA Settlements, A.F. of L. voluntarily dismissed its complaint. Notice of Voluntary Dismissal, *A.F. of L. v. Actavis, plc*, No. 15-cv-4406 (S.D.N.Y. Sept. 2, 2015), ECF 63. IPPs filed their Complaint on August 19, 2015. DPPs filed their Complaint on September 22, 2015, which they amended on October 13, 2015.

ARGUMENT

Antitrust complaints that fail to plausibly state a claim must be dismissed at the outset. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007) (courts should expose deficiencies "at the point of minimum expenditure of time and money by the parties and the court"); *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("[N]aked assertion[s]," "[t]hreadbare recitals of the elements of

a cause of action," and "mere conclusory statements" are insufficient to survive dismissal). The Supreme Court has emphasized the particular importance of this standard in antitrust cases because "[t]he costs of modern federal antitrust litigation and the increasing caseload of the federal courts counsel against sending the parties into discovery when there is no reasonable likelihood that the plaintiffs can construct a claim." *Twombly*, 550 U.S. at 558. The Second Circuit likewise has recognized that "while judges should 'be cautious before dismissing an antitrust complaint in advance of discovery,' they must also keep in mind that 'proceeding to antitrust discovery can be expensive.' . . . Accordingly, district courts 'retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed.'" *In re Elevator Antitrust Litig.*, 502 F.3d 47, 50 n.4 (2d Cir. 2007) (citing *Twombly*, 550 U.S. at 558).

I. PLAINTIFFS FAIL TO STATE A CLAIM FOR PRODUCT HOPPING

A. Plaintiffs Fail To State A Claim For A Hard Switch Product Hopping Violation Because The Preliminary Injunction Prevented the Hard Switch or Any Alleged Exclusionary Conduct

Plaintiffs allege "product hopping" or a "hard switch"—i.e., the introduction of a new product and withdrawal of an older product to force consumers to switch.[15] DPP ¶¶ 53, 86; IPP ¶ 94. But Plaintiffs do not and cannot claim that Forest actually withdrew Namenda IR. Whatever concerns Plaintiffs may have about Forest's plans,[16] the injunction prevented Forest

[15] Plaintiffs' "product hopping" claims are not asserted against Merz, nor could they be, as Plaintiffs do not allege any conduct by Merz related to the hard switch allegations. *See* DPP ¶¶ 237-257; IPP ¶¶ 191-203.

[16] Forest maintains that its plan was both lawful and procompetitive and should have been permitted by the courts.

from withdrawing Namenda IR or changing its distribution.[17] Plaintiffs instead allege that by announcing a *plan* to withdraw its older product, entering into a nationwide home delivery contract, and otherwise taking certain prefatory steps necessary to transition Namenda IR, Forest "effectively" withdrew the product, notwithstanding that Namenda IR has always been available at the local pharmacy. DPP ¶¶ 87, 238; *see also* IPP ¶¶ 95, 195. Plaintiffs' theory is at odds with the Second Circuit's holding in *Namenda II*, as well as long-standing Second Circuit precedent in *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263 (2d Cir. 1979), and the holdings of every other court to consider this issue. Finally, Plaintiffs' allegation that Namenda XR was introduced at a time when Forest believed it would have the most competitive impact cannot state an antitrust claim, as antitrust law does not interfere with a competitor's choice of how and when to introduce new products. Plaintiffs' attempt to allege a product hopping claim where there was no hop therefore must be dismissed.

1. Plaintiffs Fail to Allege the Required Exclusionary Conduct Element of a Section 2 Violation

To state a claim under Section 2 of the Sherman Act, Plaintiffs must plead: (a) anticompetitive conduct, and (b) a substantially adverse impact on competition in a relevant market. *See, e.g.*, *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004); *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456, 459 (1993); *United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 238 (2d Cir. 2003). Anticompetitive or exclusionary conduct is conduct "which prevents actual or potential rivals from competing or impairs their opportunities to do so effectively." *Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146, 150 (D.D.C. 2008) (internal quotation marks and citation omitted). Plaintiffs must therefore allege

[17] Plaintiffs seek to piggyback on the NYAG case, citing liberally to the district court and appellate court record (*e.g.*, DPP ¶¶ 12 n.8, 154 n.28, 166 n.34; IPP ¶¶ 9, 107 n.10, 111 n.13), while largely *ignoring* that the goal and result of the NYAG case was to *prevent any hard switch*.

sufficient facts to establish "an *actual* adverse effect on competition" caused by the alleged exclusionary conduct. *Capital Imaging Assocs. v. Mohawk Valley Med. Assocs.*, 996 F.2d 537, 543 (2d Cir. 1993) (emphasis in original). Absent such allegations, dismissal is appropriate. *Trinko*, 540 U.S. at 407 (upholding dismissal of complaint for failure to state a claim for monopolization). States generally follow cases interpreting the federal antitrust laws. Thus, the analysis is the same for IPPs' state law claims.[18]

2. Plaintiffs Cannot State a Claim Based on a "Hard Switch" Because The Injunction Enjoined the Alleged Hard Switch Before It Occurred, and Their Fallback "Soft Switch" Claim Is at Odds with Longstanding Precedent in this Circuit

Plaintiffs ask this Court to break new ground, to contravene established precedent, and to condemn Forest's conduct, which at most could be considered a lawful "soft switch"—an attempt to convince customers to move from one product to another, an everyday method of competition. The Court should reject this invitation, as all prior courts have done.

First, it is undisputed that there was no hard switch—Plaintiffs admit that due to the injunction Namenda IR was never withdrawn from the market. *See, e.g.*, DPP ¶ 186 (acknowledging the trial court "granted an injunction requiring Forest . . . to *continue* to make Namenda IR tablets *available* until thirty day after July 11, 2015") (emphasis added); IPP ¶ 139 (same). By its terms, the injunction prevented Forest from discontinuing the sale or limiting the supply of Namenda IR prior to generic entry in July 2015. DPP ¶ 186; IPP ¶ 139. The Second Circuit has long held that no Section 2 cause of action can arise where the conduct at issue does not actually occur, as was the case here. *See, e.g.*, *Berkey Photo*, 603 F.2d at 295 ("[A]

[18] *See*, *infra*, Section VI discussing IPPs' state law claims. As discussed in Section VI.B, certain states do not even recognize claims for unilateral action, so IPPs' product hopping claims in those states must be dismissed. *See* Kan. Stat. Ann. § 50-132; N.Y. Gen. Bus. Law § 340(1); Tenn. Code Ann. §§ 47-25-101 to 112.

purchaser . . . is not harmed until the monopolist actually exercises its illicit power to extract an excessive price. . . . And if the monopolist never consummates its scheme . . . the purchaser has no cause of action.").

Clearly lacking an actual hard switch, Plaintiffs instead allege Forest's *proposed* home delivery contract with Foundation Care somehow constituted a hard switch. DPP ¶ 87 (Forest's signing Foundation Care contract part of "implementing" hard switch); IPP ¶ 95 (same). But, as Plaintiffs also admit, Forest *never implemented* distribution through Foundation Care because it was prohibited by the injunction. *See, e.g.*, DPP ¶ 186; IPP ¶ 139; Order ¶¶ 1, 3, *New York v. Actavis, plc*, No. 14-CV-7473 (S.D.N.Y. Dec. 15, 2014), ECF 84 (requiring Forest "to *continue* to make Namenda IR . . . *available* on the same terms and conditions" and prohibiting imposition of a "'medical necessity' requirement") (emphasis added).

Because there was no hard switch, Plaintiffs must rely instead on a "soft switch" theory. A "soft switch" refers to a competitor's use of marketing, promotion and pricing to convince customers to switch to a new product. *See Namenda II*, 787 F.3d at 648. But most drug companies "try to engineer a 'soft switch'" (DPP ¶ 86), and *Namenda I* acknowledged that soft switches are typical. *See Namenda I*, 2014 WL 7015198, at *32 (describing soft switch as "the industry practice when introducing a new drug"). Plaintiffs claim that Forest "willfully and unlawfully maintained its monopoly power" by "coerc[ing] the conversion of the Memantine Hydrochloride Market from Namenda IR to Namenda XR." DPP ¶ 238; *see also* IPP ¶ 195 ("Forest unlawfully switched the conversion of the memantine hydrochloride market from Namenda IR to Namenda XR"). Plaintiffs' theory rests on the characterization that Forest "effectively" withdrew Namenda IR—notwithstanding that anyone could buy it at the local pharmacy at all relevant times. As support, Plaintiffs point to: (1) the February 2014

announcement that Namenda IR would be discontinued in the future; and (2) Forest's request that the Centers for Medicare and Medicaid Services ("CMS") remove Namenda IR from their reference list for 2015 in anticipation of discontinuance. DPP ¶¶ 87, 238; *see also* IPP ¶¶ 95, 195.

As a threshold matter, Plaintiffs' overall theory is facially questionable: that Forest could be liable merely for (a) publicly and truthfully announcing a future plan to transition away from Namenda IR, followed by subsequent announcements (pursuant to court order) that Namenda IR would be left on the market, and (b) informing CMS of its proposed plans. To the extent that any doctors prescribed Namenda XR as a result of the announcement, pharmaceutical promotion to doctors is protected commercial speech under the First Amendment. *See Sorrell*, 131 S. Ct. at 2665, 2659. And petitioning of the government is also protected speech as well, immune from antitrust challenges. *See Prof'l Real Estate Inv'rs,* 508 U.S. at 56; *E. R. R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 138 (1961) (Sherman Act not intended "to invade" First Amendment rights).

But, even if Forest's actions could be construed as attempting to convince patients to switch to Namenda XR while Namenda IR remained on the market, and even if this speech were somehow outside of First Amendment commercial speech, this sort of competition is specifically allowed by the Second Circuit. *Namenda II*, 787 F.3d at 648 ("As long as Defendants sought to persuade patients and their doctors to switch from Namenda IR to Namenda XR while both were on the market (the soft switch) and with Generic Namenda IR drugs on the horizon, patients and doctors could evaluate the products and their generics on the merits in furtherance of competitive objectives.").

a. The Mere Announcement of Potential Discontinuation of Namenda IR Is Not Exclusionary Conduct

The Second Circuit's holding in the NYAG case is consistent with a long line of precedent in this and other circuits in rejecting the idea that advertising, marketing, or other similar competitive steps in support of a new product can be considered anticompetitive. These cases draw a clear line between trying to convince customers to choose one product over another and coercing them to do so. As a starting point, the Second Circuit held in *Berkey Photo* that there is no coercion associated with new product introduction where the older version of the product remains available in the market. 603 F.2d at 287. In *Berkey Photo*, the plaintiff alleged that Kodak's dual marketing of a compatible camera and film coerced customers to purchase the camera because the film was not compatible with any other camera models. *Id*. at 286. The Second Circuit rejected this argument, holding that "the mere introduction of Kodacolor II along with the Pocket Instamatics did not coerce camera purchasers" because "Kodak did not remove any other films from the market when it introduced the new one." *Id*. at 287. The court rejected the argument that merely advertising new film as "remarkable" was sufficient to coerce customers where they remained free to choose between the new camera system and the old. *Id.*; *see also Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 1002 (9th Cir. 2010) (affirming dismissal where customers were not forced to purchase new product).

Every court to consider the issue since *Berkey Photo* has similarly refused to find that the mere introduction of a new product can be anticompetitive, even when combined with advertising or public statements—instead holding that there is no coercion and no exclusionary conduct under Section 2 if the old product remains on the market. For example, in *Walgreen Co. v. AstraZeneca Pharm. L.P.*, the District Court for the District of Columbia dismissed allegations based on the brand manufacturer's efforts to switch customers before generic entry. 534 F.

Supp. 2d at 148. As here, the plaintiffs in *Walgreen* alleged that the brand manufacturer "ceased promoting and detailing" the older product after launching its new versions. *Compare* 534 F. Supp. 2d at 149, *with* DPP ¶ 153; IPP ¶ 105. And, as here, the plaintiffs alleged that because there was "almost no difference between [the newer product] and [the older product]," defendant's efforts to convince customers to switch were "exclusionary." *Compare* 534 F. Supp. 2d at 149, *with* DPP ¶¶ 159-161; IPP ¶¶ 112-14. The *Walgreen* court rejected both arguments, holding that the plaintiffs had failed to allege anticompetitive conduct because "there is no allegation that [the brand] eliminated any consumer choices. Rather, [the brand] added choices." 534 F. Supp. 2d at 151. When related claims were brought in this district, Judge Jones agreed they were meritless and similarly granted dismissal on motion to dismiss. *AstraZeneca AB v. Mylan Labs. Inc*., Nos. 00 Civ. 6749, 03 Civ. 6057, 2010 WL 2079722, at *6 (S.D.N.Y. May 19, 2010) (plaintiff "failed to plausibly allege 'predatory or exclusionary acts or practices that have the effect of preventing or excluding competition within the relevant market,' . . . because the alleged conduct—introducing new products—is generally considered pro-competitive"); *see also Oahu Gas Serv., Inc. v. Pac. Res. Inc.*, 838 F.2d 360, 369 (9th Cir. 1988) (A "line of 'product innovation' cases has consistently rejected antitrust liability for a monopolist's decision about when or whether to market new products.").

Likewise, in *In re Solodyn (Minocycline Hydrochloride) Antitrust Litigation*, the court granted dismissal because plaintiffs could not plausibly allege that introducing a new strength restrained consumer choice where the prior versions remained on the market. No. 14-md-02503, 2015 WL 5458570, at *13, *21 (D. Mass. Sept. 16, 2015). By comparison, in *Abbott Labs. v. Teva Pharm. USA, Inc.*, the court permitted claims to survive dismissal only because defendants "allegedly prevented [a choice between formulations] by removing the old formulations from the

market while introducing new formulations." 432 F. Supp. 2d 408, 422 (D. Del. 2006); *see also Walgreen*, 534 F. Supp. 2d at 151 ("The elimination of choice was a critical factor in the court's decision to deny Abbott's motion to dismiss" in the *Abbott* case). Because it is undisputed that Forest never removed Namenda IR from the market, dismissal is required.

Injunction Preserved Choice. Plaintiffs do not allege that Forest failed to comply with any portion of the injunction, and the NYAG (who monitored compliance) agreed. In the settlement agreement, the NYAG stated that it "is unaware of any violation of the injunction by Allergan"—Forest's parent company. NYAG Settlement at 3. New York acknowledged that the injunction "prevented Allergan from removing Namenda IR from the market, or limiting the distribution of Namenda IR, and during the Injunction term and afterwards Allergan has continued to manufacture and supply Namenda IR, thus permitting patient access at all times to Namenda IR in all 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, and Guam[.]" *Id*. at 2. Moreover, New York recognized that the "[i]njunction was effective in protecting competition in the relevant market and permitting lower cost generic drugs to enter the market in July 2015 and subsequently." *Id*. at 2, 3. And, other than limited litigation costs, the NYAG dismissed the case and did not require any payment of damages for either direct or indirect purchasers of Namenda in New York. *Id*. at 5.

Commercial Speech Protected. Courts have long held that truthful public statements are not themselves anticompetitive under the First Amendment. Speech is protected, regardless of whether the motivations behind such speech are self-interested or harmful to competitors. *Sorrell*, 131 S. Ct. at 2659 ("Speech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment."); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 496 (1996) ("[T]he First Amendment protect[s] the dissemination

of truthful and nonmisleading commercial messages about lawful products and services[.]"). Forest is alleged only to have announced the truth—that it was planning to withdraw Namenda IR, which it believed (and believes) to be permissible under the antitrust laws. There can be no liability merely for truthfully announcing an intended course of conduct, even if that course is ultimately blocked. *See MCI Commc'ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1129 (7th Cir. 1983) (holding that a "press release [did not] contain[] any false or misleading information about Hi-Lo or its availability" and an "announcement . . . must be found to be knowingly false or misleading before it can amount to an exclusionary practice"); *Berkey Photo*, 603 F.2d at 287-88 (noting commercial speech "does not, at least unless it amounts to deception, constitute anticompetitive conduct violative of [Section 2]"); *see also U.S. Football League v. Nat'l Football League*, 634 F. Supp. 1155, 1183 (S.D.N.Y. 1986) ("[t]he mere dissemination of unflattering opinion or information about a competitor, unaccompanied by misstatements of fact, simply does not amount to a violation of the antitrust laws.").

(i) Plaintiffs' Allegations Enjoy No Support in Dicta from New York v. Actavis

Plaintiffs misinterpret a passing remark in the Second Circuit's opinion in *Namenda II* to suggest that the mere announcement that Namenda IR would be discontinued in the future is "tantamount" to withdrawal of the product. DPP ¶ 174; IPP ¶ 127. There, the Second Circuit held that, *assuming that* Forest *had* removed Namenda IR from the market, the combination of introducing Namenda XR, announcing the discontinuation of Namenda IR, *and* limiting the distribution of Namenda IR to a single pharmacy, the District Court did not abuse its discretion in concluding that the plaintiff had established a substantial likelihood of success on the merits. *Namenda II*, 787 F.3d at 648. The Second Circuit observed, however, that this conduct was "suspended" in light of the litigation—and ultimately enjoined. *Id.* Plaintiffs' allegation is not

supported by either *Namenda I* or *Namenda II* because neither court found that Forest's mere announcement of the discontinuation standing alone amounted to exclusionary conduct.

The Second Circuit's statement that an announcement of discontinuation is tantamount to withdrawal must be read in the context of the procedural posture of the case. The court was assessing the District Court's finding of likelihood of success on the merits and irreparable harm assuming the hard switch had taken place. *Id.* at 650. Plaintiffs' artful pleading ignores the fact that that very decision prevented the conduct that the court was evaluating. The District Court found that the anticompetitive conduct at issue was the *potential* for actual discontinuance or limitations on distribution—not the mere announcement of discontinuance in the future. *See Namenda I*, 2014 WL 7015198, at * 39 (finding plaintiff "demonstrated a substantial risk that Defendants' limited distribution strategy would harm competition in the memantine market"); *see also id*. at *32 ("If Defendants are allowed implement their hard switch strategy . . ."). Accordingly, the District Court found that the injunction would prevent the hard switch and "maintain the status quo," which is "consistent with an accepted industry practice of a soft switch when a new product is introduced, a practice that maintains consumer choice before and after generic entry into the market." *Id*. at *43.

Plaintiffs also ignore that the Second Circuit expressly recognized that the District Court's findings of fact at the preliminary injunction stage were *forward-looking* statements about potential harms that could have resulted *if* the hard switch had been brought to fruition. *E.g.*, *Namenda II*, 787 F.3d at 649 ("*If* Defendants forced Alzheimer's patients to switch to Namenda XR prior to generic entry . . .") (emphasis added); *see also id*. at 655 (Defendants' hard switch *would likely have* anticompetitive and exclusionary effects on competition in the memantine market . . .") (emphasis added); *see also id*. at 661 (observing that the District Court

found that "Defendants' hard switch *would cause* economic harm" because consumers and third party payors "*would pay*" more for memantine therapy "*if* Defendants were permitted to switch patients to Namenda XR before generic IR entry") (emphases added); *see also id*. at 648 (recognizing Forest agreed to litigation "standstill" agreement whereby Forest agreed not to take any action to withdraw Namenda IR from the market).

In short, Plaintiffs' theory that the mere announcement of planned discontinuation is tantamount to withdrawal and constitutes exclusionary conduct enjoys no support in *Namenda I* and *Namenda II*.

(ii) Plaintiffs Fail Plausibly to Allege That the February 2014 Announcement Caused Switching

Dismissal is also appropriate because Plaintiffs' allegation that the mere announcement caused a "wave of conversion" is not plausible. DPP ¶ 185; IPP ¶ 138. In support of this allegation, Plaintiffs inexplicably focus on a 17-month period: "From January 2014 to May 2015, the conversion rate increased from 15% or less to about 50% in anticipation of the lack of availability of Namenda IR." DPP ¶ 185 (citing transcripts from earning calls); IPP ¶ 138. First, this time period starts *before* Forest announced the discontinuance of Namenda IR. Plaintiffs cannot attribute any conversion between January 1, 2014 and February 14, 2014 to coercion because it was *prior to* the announcement. The more plausible explanation for the pre-February 14, 2014 switching is patient and doctor excitement about the new once-daily XR formulation.

Second, Plaintiffs' 17-month time period extends 6 months past the December 15, 2015 injunction, when Forest was required to notify the world that Namenda IR would in fact remain on the market. Order ¶ 2, *New York v. Actavis, plc*, No. 14-cv-07473 (S.D.N.Y. Dec. 15, 2014), ECF 84 ("Defendants shall inform healthcare providers, pharmacists, patients, caregivers, and health plans of this injunction (and provide a copy of the injunction or other means to easily view

the injunction) and the continued availability of Namenda IR in the same or substantially similar manner in which they informed them of Defendants' plan to discontinue Namenda IR in February 2014."). This forecloses an inference that any conversion through May 2015 was attributable to the February 2014 announcement.

In fact, after the announcement that Namenda IR would remain on the market, conversion from Namenda IR to XR continued. Conversion as of February 6, 2015 was 43%[19] and, by Plaintiffs own allegations, as of May 11, 2015, the conversion rate was 49%. DPP ¶ 185 n.45 (citing Actavis 1Q 2015 earnings call transcript (May 11, 2015)); IPP ¶ 138 n.26. If patients were switching to Namenda XR only because they were coerced to do so, switching would have halted after the injunction. The fact that patients continued to switch to Namenda XR after the injunction renders implausible Plaintiffs' allegation that the conversion to Namenda XR was "in anticipation of the lack of availability of Namenda IR." *See* DPP ¶ 185; IPP ¶ 139.

It is more plausible that the December 2014 to May 2015 conversion was driven instead by Namenda XR's lower price and product enhancements drove incremental conversion as Namenda XR competed in the market. Plaintiffs concede that *Namenda XR was priced lower* than Namenda IR prior to Generic Namenda IR entry (DPP ¶ 157), and that Namenda XR provided once-daily dosing in contrast to twice-daily Namenda IR (DPP ¶ 144, IPP ¶ 87). The Second Circuit recognized that Forest "sold XR at a discounted rate, making it considerably less expensive." *Namenda II*, 787 F.3d at 648. Plaintiffs also acknowledge that Forest had an "aggressive marketing campaign" to educate patients, doctors, insurers and others about the benefits of the newly formulated Namenda XR. DPP ¶ 153; IPP ¶ 105 (same). And courts have

[19] Actavis 4Q 2014 earnings call transcript (Feb. 20, 2015), http://seekingalpha.com/article/2937346-actavis-act-ceo-brent-saunders-on-q4-2014-results-earnings-call-transcript.

recognized the benefits to patients of once-daily administrations over twice-daily treatment. *See Billhofer v. Flamel Techs., S.A.*, No. 07 Civ. 9929, 2012 WL 3079186, at *12 (S.D.N.Y. July 30, 2012) (finding in an action involving once- and twice-daily products, that it "is essentially tautological" that "reduced medication dosing provides patients a convenience benefit and leads to improved patient compliance" because "more convenient dosing regimens have obvious benefits") (internal quotation marks omitted).

Therefore, it is more plausible that patients, doctors, insurance companies and other purchasers were switching to Namenda XR based on its advantages, increased adoption by the medical community, and Forest's marketing of the product. *See Twombly*, 550 U.S. at 570 (complaint must include "enough facts to state a claim to relief that is plausible on its face"). Persuading a purchaser to switch to Namenda XR through advertising its benefits and providing discounts is the essence of procompetitive behavior. *See Sorrell*, 131 S. Ct. at 2664-67, 2679; *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.,* 475 U.S. 574, 594 (1986) ("cutting prices in order to increase business often is the very essence of competition"); *Berkey Photo*, 603 F.2d at 287-88 (monopolist engaging in "[a]dvertising that emphasizes a product's strengths" is consistent with permissible competitive conduct absent coercion).

b. Plaintiffs Do Not Allege That the Request to CMS Lessened Competition And, In Any Event, the Request Is Protected Speech Under The *Noerr-Pennington* Doctrine

Plaintiffs also claim that Forest's notice to CMS and request to remove Namenda IR from the Formulary Reference File ("FRF") somehow coerced conversion to Namenda XR. DPP ¶¶ 179, 238; IPP ¶¶ 132, 195. However, Plaintiffs do not allege that CMS in fact did remove Namenda IR from FRF for 2015, nor do Plaintiffs articulate how Forest's notice harmed competition. Instead, Plaintiffs baselessly speculate that removal *would* make health plans less

likely to cover Namenda IR. DPP ¶ 179 (based on CMS notice health plans "*were more likely to discontinue* covering Namenda IR") (emphasis added); IPP ¶ 132 (same). But Plaintiffs' vague allegations fail to state any causal link between Forest's actions and (1) the contents of the 2015 FRF, or (2) the health plan coverage of Namenda IR. Indeed, the intervening decision-making of both CMS and Medicare Part D sponsors make such a link impossible. First, CMS makes its own evaluations regarding which drugs to list on the FRF, "routinely monitor[ing] for product-related changes" including "[v]oluntary manufacturer product discontinuation."[20] Second, once CMS has chosen which drugs to include on the FRF, "Part D sponsors are ultimately responsible for making coverage determinations and should not necessarily include or exclude a drug product from coverage based solely on the presence or absence of an [drug] on the FRF." *Id.* Should a Part D sponsor believe that a drug should be added, it can request that CMS do so. *Id.* Thus, there is no direct causal link between Forest's suggestion that Namenda IR be removed from the FRF due to its then-anticipated discontinuation and any switching to Namenda XR—nor is such a link alleged. *See Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 533 n.26 (1983) ("*AGC*") (plaintiff must show a "causal connection" between conduct and injury).

Moreover, Forest's communications with CMS enjoy antitrust immunity as petitioning activity protected by the First Amendment under the *Noerr-Pennington* doctrine, which extends to communications with government agencies such as CMS. *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510-11 (1972). The FRF is maintained by CMS and its content is the

[20] Formulary Reference File FAQ (Apr. 8, 2014), http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_FormularyGuidance.html.

result of CMS review and approval.[21] "'[W]here a restraint upon trade or monopolization is the result of valid governmental action, as opposed to private action,' those urging the governmental action enjoy *absolute immunity* from antitrust liability for the anticompetitive restraint." *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988) (emphasis added) (quoting *Noerr*, 365 U.S. at 136); *accord City of Columbia v. Omni Outdoor Adver., Inc.*, 499 U.S. 365 (1991) (city and competitor immune from antitrust laws for activities relating to enactment of ordinances because "[t]he federal antitrust laws . . . do not regulate the conduct of private individuals in seeking anticompetitive action from the government"). Any request by Forest petitioning CMS to take an action is clearly protected conduct under the *Noerr-Pennington* precedents. *See Miracle Mile Assocs. v. City of Rochester*, 617 F.2d 18, 20 (2d Cir. 1980) ("[M]ere solicitation of governmental action . . . is an activity which is fully protected by the First Amendment and is immune from Sherman Act liability[.]"). Plaintiffs' allegation based on such petitioning conduct must therefore be dismissed.

3. Plaintiffs' Claim Based on the Timing of the Introduction of Namenda XR Is Contrary to the Fundamental Purposes of the Antitrust Laws, Such as Promoting Innovation

Plaintiffs next allege without support that the timing of Forest's introduction of Namenda XR was deliberately done to "avoid prematurely cannibalizing sales of Namenda IR." DPP ¶¶ 13, 147-149. Notwithstanding that Plaintiffs' vague allegation proposes no metric for determining when Forest "should" have introduced its new product, the Second Circuit has made clear that "any firm, even a monopolist, may generally bring its products to market whenever and however it chooses." *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 286 (2d Cir. 1979); *see also Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 775 (1984) ("Subjecting a

[21] Formulary Reference File FAQ (Apr. 8, 2014), http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_FormularyGuidance.html.

single firm's every action to judicial scrutiny for reasonableness would threaten to discourage the competitive enthusiasm that the antitrust laws seek to promote."). Choosing when to introduce a new product to best take advantage of market conditions is a quintessential form of competition, and a claim based on the assumption that Forest is required to bring products to market when it is better for competitors, rather than when it is better for *Forest*, is one that rejects the idea of competition entirely. *See Berkey Photo*, 603 F.2d at 286.

B. Plaintiffs Fail To Sufficiently Plead Standing To Bring A Claim For The Alleged Product Hop From Namenda IR To Namenda XR

Plaintiffs' product hopping claims also fail because Plaintiffs lack standing, as they suffered no antitrust injury here.

1. Plaintiffs Fail to Plead Injury in Fact Required For Article III Standing

In an antitrust case, a plaintiff must have constitutional standing under Article III, as well as antitrust standing. *See AGC*, 459 U.S. at 535 n.31; *see also Port Dock & Stone Corp. v. Oldcastle Ne., Inc.*, 507 F.3d 117, 121 (2d Cir. 2007). To satisfy Article III standing a plaintiff must establish that: (1) he or she suffered an "injury in fact"; (2) there is a causal connection between the injury and the defendant's actions; and (3) the injury can be redressed by a favorable decision for the plaintiff. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). An injury in fact is "an invasion of a legally protected interest which is (a) concrete and particularized . . . and (b) actual or imminent, not conjectural or hypothetical . . . ." *Id*. (internal quotation marks and citations omitted); *see also* 15 U.S.C. § 15 (limiting private actions under the Sherman act to "any person who shall be injured in his business or property").

Plaintiffs fail to allege an injury-in-fact to their business or property caused by the product hop claim because the product hop never happened and was specifically enjoined by the

injunction. Plaintiffs claim that as a result of Forest's "conversion of the market from the IR to the XR formulation" they paid "supra-competitive prices" for Namenda XR. DPP ¶¶ 237-243; *see also* IPP ¶¶ 193-198. Yet, elsewhere in their Complaints, Plaintiffs concede that "[t]hroughout the two-year period that Namenda XR was on the market prior to generic launch" Forest priced Namenda XR product "at a 5% discount off of the Namenda IR WAC price." DPP ¶ 157; *see also* IPP ¶ 110. Further, Plaintiffs admit that "Forest agreed to pay rebates to health plans to make sure they put Namenda XR on the same [formulary] tier as Namenda IR" and that "patients did not have to pay higher co-payments for Namenda XR" prior to Generic Namenda IR entry into the market. DPP ¶ 157; IPP ¶ 110; *see also Namenda II*, 787 F.3d at 648 (Forest "sold XR at a discounted rate, making it considerably less expensive"). Moreover, as Plaintiffs readily admit, upon massive Generic Namenda IR entry in July 2015, "the price of Generic Namenda IR quickly plummeted to less than 10% of the July 2015 Namenda IR brand [price]." DPP ¶ 118 n.2. Therefore, by Plaintiffs' own allegations, they never paid supra-competitive prices for Namenda XR prior to Generic Namenda IR entry into the memantine market in July 2015, nor did they pay supra-competitive prices for memantine after Generic Namenda IR entry.

Because Plaintiffs never paid supra-competitive prices for Namenda XR, they cannot plausibly allege that they ever paid any overcharge that was independently attributable to the introduction of admittedly cheaper Namenda XR or the planned but never-consummated "hard switch." Indeed, Plaintiffs' theory of damages rests entirely on the allegation that the ANDA Settlements delayed entry. Plaintiffs' damages are purportedly the cost difference between the Namenda they purchased in the real world and what they would have paid for the generic version in a hypothetical but-for world. Thus for Plaintiffs to state an overcharge claim for the introduction of Namenda XR, there must be a generic version of Namenda that would have been

available for them to purchase if not for Defendants' conduct. But it is uncontested that no such generic was on the market until July 2015, and Plaintiffs do not contend that the launch of Namenda XR delayed generic entry in any way. *See* DPP ¶ 14; IPP ¶ 11.

Even if Plaintiffs are correct—and they are not—that but for the ANDA Settlements, Generic Namenda IR would have launched as early as 2010, the introduction of Namenda XR in 2013 still would not create any independent overcharge. Because Plaintiffs concede Namenda XR was less expensive than Namenda IR, DPP ¶ 157; IPP ¶ 110, any switching to Namenda XR before July 2015 would actually have *reduced* any supposed overcharge. Plaintiffs cannot allege any independent harm attributable to Defendants launch of a *less expensive* version of Namenda prior to July 2015.

Similarly, Plaintiffs cannot claim they were overcharged after July 2015 because, by then, patients, physicians, and insurers were free to choose from Namenda IR, Namenda XR, and Generic Namenda IR. Any prescription filled for Namenda XR after July 2015 is not an overcharge; rather, it is evidence of a customer's decision to forego the cost savings of a twice-daily Generic Namenda IR in favor of the benefits of once-daily Namenda XR. Plaintiffs' strained attempt to characterize the market's decision not to switch from Namenda XR to Generic Namenda IR after July 2015 as an "overcharge" cannot save Plaintiffs' "product hopping" claim from dismissal where both products were available in the market.

Even if Plaintiffs could plausibly allege actual injury—which they cannot—such injury is too speculative to recover under the antitrust laws. *See AGC*, 459 U.S. at 543 (plaintiff not a person injured by reason of a violation of the antitrust laws within the meaning of § 4 of the Clayton Act where "nothing but speculation informs the [plaintiff's] claim of injury by reason of the alleged unlawful coercion"). As discussed above, *supra* Section I.A.2, there is no plausible

allegation of "conversion of the market" simply based on Forest's announcement of its intention to withdraw Namenda IR, followed by its announcement that the product would remain on the market. As such, Plaintiffs have failed to plead a sufficient basis for standing to bring claims for a violation of the Sherman Act for the alleged conversion of the market from IR to XR formulation.

2. Increased Competition from Namenda XR Introduction Is Not Antitrust Injury

Although there is no need to proceed to an antitrust standing analysis where, as here, Plaintiffs have failed to establish Article III standing, *see Ross v. Bank of Am., N.A.*, 524 F.3d 217, 222 n.1 (2d Cir. 2008), even if Plaintiffs could establish Article III standing, they cannot establish antitrust injury because the introduction of a new product by definition *increases* competition in the relevant market. *See AstraZeneca AB*, 2010 WL 2079722, at *6 ("introducing new products . . . is generally considered pro-competitive"); *Eon Labs Mfg., Inc. v. Watson Pharm., Inc.*, 164 F. Supp. 2d 350, 358 (S.D.N.Y. 2001) (antitrust injury not sufficiently pled where claim alleged generic entry through improper means). And the antitrust laws are not meant to address conduct that increases competition in a market. *See Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 343-44 (1990) ("The antitrust injury requirement ensures that a plaintiff can recover only if the loss stems from a competition-reducing aspect or effect of the defendant's behavior."); *Balaklaw v. Lovell*, 14 F.3d 793, 797 (2d Cir. 1994) ("It follows from the purposes of the antitrust laws that injuries resulting from competition alone are not sufficient to constitute antitrust injuries."). Plaintiffs fail to plausibly allege anyone was coerced into buying Namenda XR. So, any purchases of Namenda XR were the result of patient and physician choices. Absent coercion, plaintiffs cannot establish antitrust injury through any competition-reducing aspect of Forest's introduction of Namenda XR. *See, e.g.*, *Walgreen*, 534

F. Supp. 2d at 152 (no antitrust injury from introduction of new competitive product; "The fact that a new product siphoned off some of the sales from the old product and, in turn, depressed sales of the generic substitutes for the old product, does not create an antitrust cause of action").

II. THE ANDA SETTLEMENT AGREEMENTS DO NOT GIVE RISE TO REVERSE PAYMENT ANTITRUST CLAIMS

To preserve the longstanding balance between patent and antitrust, and protect the ability of parties to settle patent litigation, the Supreme Court in *FTC v. Actavis* drew a distinction between traditional, commonplace, and often mutually-beneficial settlements, on the one hand, and unlawful reverse payments, on the other. In creating a limited exception—unlawful reverse payments—to the general rule that settlement agreements are procompetitive, the Court "did not intend to alter" the rule that commonplace forms of settlement are *not* subject to antitrust scrutiny. *Actavis*, 133 S. Ct. at 2233. Indeed, *Actavis* reflects a strong policy in favor of settlement. *See, e.g.*, *Actavis*, 133 S. Ct. at 2234 (recognizing importance of settlement); *Wygant v. Jackson Bd. of Educ.*, 476 U.S. 267, 305 (1986) ("general policy in favor of settlements").

Courts must apply the distinction between commonplace settlements and unlawful reverse payment settlements at the motion to dismiss stage because if protracted antitrust litigation follows every patent settlement, parties will be highly disincentivized to settle patent cases. *See Kimble v. Marvel Entm't LLC*, 135 S. Ct. 2401, 2411 (2015) (rejecting application of antitrust rule of reason analysis in part because "whatever its merits may be for deciding antitrust claims, that 'elaborate inquiry' produces notoriously high litigation costs and unpredictable results"); *see also Actavis*, 133 S. Ct. 2243 (Roberts, C.J., dissenting) ("Simply put, there would be no incentive to settle if, immediately after settling, the parties would have to litigate the same issue."). Because Plaintiffs fail to allege any unlawful reverse payments in the challenged settlements, their reverse payment claims must be dismissed.

A. Plaintiffs Have Not Alleged Any "Large" And "Unjustified" Reverse Payment To Generic Competitors, Nor Could They

The Supreme Court held in *Actavis* that settlements containing "reverse payments" from the patent holder to the generic are not presumptively unlawful, and only where such reverse payments are "large and unjustified" do they potentially give rise to antitrust concerns. 133 S. Ct. at 2237; *see also Actos*, 2015 WL 5610752, at *14 ("[A] reading of *Actavis* that would compel antitrust scrutiny of a settlement regardless of whether its terms could reasonably be construed as a large and unjustified reverse payment would ignore the limiting principles set forth in the decision, and subject virtually *any* settlement to antitrust scrutiny – a result the Court could not have intended."). A settlement agreement therefore triggers antitrust concerns under *Actavis* only if it contains (1) a "payment," (2) that is "reverse," (3) that is "large," and (4) that is "unjustified." *Actavis*, 133 S. Ct. at 2237; *see also Actos*, 2015 WL 5610752, at *11.

Plaintiffs bear the initial burden of pleading the existence of a large and unjustified reverse payment. *Actos*, 2015 WL 5610752, at *19 ("[T]o meet their pleading burden as to whether the payments were 'large' and 'unjustified,' Plaintiffs must plausibly allege a factual basis for the Court to reasonably estimate the value of the settlement terms.").

Here, Plaintiffs have alleged virtually nothing about reverse payments, instead relying on speculation. *See* DPP ¶ 112 ("Each of the Potential First-Filing Generics would have to receive something of immediate and substantial value (such as cash and/or protection from competition with each other) in order to induce them to forego their right to profit from the sale of their generic versions of immediate release Namenda tablets."); *id.* ¶ 119 ("On information and belief, the value of Forest and Merz's aggregate payments to all of Potential First-Filing Generics pursuant to the Contingent Entry Agreements total many millions of dollars."); IPP ¶ 76 ("As rational economic actors who filed ANDAs seeking early entry into the market, these generic

companies very likely received something of value in exchange for the agreement to delay entry."). Such "naked assertions" and "conclusory statements" fall far short of a well-pleaded complaint. *See Iqbal*, 556 U.S. at 678 (2009).

Plaintiffs' theory appears to be that no generic company would accept a settlement in a patent case that granted only early entry—i.e., that early entry date settlements are inherently suspect under the antitrust laws. The Supreme Court disagrees: early entry settlements are not only explicitly lawful, but favored. *See, e.g.*, *Actavis*, 133 S. Ct. at 2234 ("settlement on terms permitting the patent challenger to enter the market before the patent expires *would also bring about competition, again to the consumer's benefit*") (emphasis added); *id*. at 2237 (patent litigants "may . . . settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point"). The FTC likewise disagrees with Plaintiffs' theory, having told the Supreme Court, "the parties to paragraph IV litigation *have broad freedom* to settle by agreeing upon a *compromise date* of generic entry." Reply Br. of Pet'r, *FTC v. Actavis*, No. 12-416 (U.S. Mar. 18, 2013), 2013 WL 1099171, at *8-9 (emphasis added); *cf. id.* at *9 ("[A] compromise date of market entry is a natural and generally lawful term of an agreement to settle patent litigation.") (emphasis omitted).

1. Small Payments for Avoided Litigation Costs are Not Reverse Payments Under *Actavis*

Plaintiffs' threadbare allegations are not surprising when one examines the ANDA Settlements, which plainly lack "large," "unjustified" reverse payments. *See* KO Decl. Exs. 1-11, 13; *see also supra* n.12. The only payments contained in the ANDA Settlements are routine

payments of $[redacted] or less for litigation costs and attorneys' fees.[22] *See supra* n.12. *Actavis* held that payments that "reflect traditional settlement considerations, such as *avoided litigation costs*" do not generally raise concerns about illegal monopolistic practices. 133 S. Ct. at 2236 (emphasis added). The FTC has recommended a safe harbor of up to $7 million for attorneys' fees and costs as a payment that does not present antitrust concerns. *See* FTC Press Release, FTC Settlement of Cephalon Pay for Delay (May 28, 2015), https://www.ftc.gov/news-events/press-releases/2015/05/ftc-settlement-cephalon-pay-delay-case-ensures-12-billion-ill; *see also* Order at 4, ¶ 21.a, *FTC v. Cephalon Inc.*, No. 08-cv-2141 (E.D. Pa. June 17, 2015), ECF 405 (ordering resolution of case by settlement and finding that compensation for litigation costs up to $7 million did not constitute reverse payment); *see also Actavis*, 133 S. Ct. at 2243-44 (Roberts, J., dissenting) (cost of patent infringement litigation for generic manufacturer challenging brand can be as much as $10 million per suit). Thus, the minimal payments here for costs and attorneys' fees of zero to $[redacted] can raise no inference of anticompetitive reverse payments. *See supra* n.12.

2. Generic Entry Acceleration Clauses Are Not Payments, Let Alone "Large and Unjustified" Reverse Payments

Plaintiffs imply, but do not expressly allege, that the Generic Entry Acceleration Clauses[23] constituted reverse payments. DPP ¶ 112, 131 ("Each of the Potential First-Filing Generics would have to receive something of immediate and substantial value (such as cash and/or protection from competition with each other) in order to induce them" to enter the settlement agreements); IPP ¶¶ 76, 79 (generic companies "likely received something of value"

[22] Payments for services Forest received in certain business agreements entered with generic competitors are discussed separately below. *See infra* Section II.C.

[23] Generic Entry Acceleration Clauses, which provide the potential for earlier entry, are also sometimes known as "contingent launch" clauses because earlier entry is contingent upon another qualifying generic entering the market earlier. *E.g.*, DPP ¶ 5.

in exchange for entering the agreements, and Generic Entry Acceleration Clauses "were likely the mechanism" by which generics consented to the agreements and the contingent launch provisions were "unlawful"). If Plaintiffs are alleging that such clauses are reverse payments, this claim must fail.

First, *Actavis* itself involved Generic Entry Acceleration Clauses, but the Court did not take issue with them. *See Actavis*, 133 S. Ct. at 2229 ("Under the terms of the settlement Actavis agreed that it would not bring its generic to market until August 31, 2015, 65 months before Solvay's patent expired (*unless someone else marketed a generic sooner*).") (emphasis added). Similarly, a court within this district this year analyzed substantially similar allegations with respect to Generic Entry Acceleration Clauses and held that they do not trigger antitrust scrutiny. *Actos*, 2015 WL 5610752, at *15-18 (dismissing claims based on Generic Entry Acceleration Clauses, observing that no court has ever found these routine settlement clauses to be illegal reverse payments under *Actavis*). Furthermore, the FTC specifically excluded such clauses from its definition of reverse payments in a recent consent decree. Order at 5, ¶ 21.d, *FTC v. Cephalon, Inc.*, No. 08-cv-02141 (E.D. Pa. June 17, 2015) ECF 405 (payment does not include "provisions in a Brand/Generic Settlement Agreement that permit an ANDA Filer to begin selling, offering for sale, or distributing the Subject Drug Product once another drug company begins selling, offering for sale, or distributing the Subject Drug Product").

Second, no antitrust scrutiny is warranted for such procompetitive, routine settlement terms. Generic Entry Acceleration Clauses simply allow settling generics to enter the market *even earlier* than the agreed-upon entry date in the event that another generic is permitted to launch earlier. As *Actos* aptly summarized: "An acceleration clause by its plain terms merely affects the date of entry into market," and "[t]he practical effect of [an] acceleration clause[] [is]

thus to *increase* competition." *Actos*, 2015 WL 5610752, at *16, *15 (emphasis added). Because agreements that merely affect the generic entry date are expressly identified by the Supreme Court as lawful settlements, Generic Entry Acceleration Clauses simply cannot trigger antitrust scrutiny under *Actavis*. *See Actavis*, 133 S. Ct. at 2237; *see also Actos*, 2015 WL 5610752, at *16 (acceleration clauses not unlawful under *Actavis*).

Third, Plaintiffs do not make any allegation as to the value of the Generic Entry Acceleration Clauses, and therefore fail to meet their burden under *Actavis* to show that the Generic Entry Acceleration Clauses constitute "large" reverse payments. Where plaintiffs claim that a transfer of value other than money[24] constitutes a reverse payment, they must allege its estimated value so the Court may determine whether the payment was "large." *Actos*, 2015 WL 5610752, at *13 (in order for a court to find a non-cash payment an unlawful reverse payment, it must be able to estimate the value of the term); *In re Effexor XR Antitrust Litig.*, No. 11-md-5479, 2014 WL 4988410 at *20 (D.N.J. Oct. 6, 2014) (requiring non-monetary payment to be converted to a reliable estimate of its monetary value so it may be analyzed under *Actavis*). Further, plaintiffs must present a basis for estimating the value, as "[s]imply alleging some sort of value of [an agreement], absent a reliable foundation supporting that value, does not establish the plausibility required by Rule 12(b)(6)." *Effexor*, 2014 WL 4988410, at *21; *cf. In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523, 543 (D.N.J. 2014) (establishing higher plausibility standard for alleging non-monetary payments constitute reverse payments, requiring plaintiffs to plead reliable foundation for estimating cash value of non-monetary payment).

[24] The farther away the alleged payment is from cash or cash equivalents, the more difficult the payment is to quantify; this may explain why some district courts have held that a reverse payment does not warrant scrutiny unless it is in the form of cash. *See In re Loestrin 24 Fe Antitrust Litig*, 45 F. Supp. 3d 180, 192 (D.R.I. 2014).

B. Plaintiffs Cannot Allege Antitrust Injury Caused By ANDA Settlement Agreements

Pursuant to Section 4 of the Clayton Act, private plaintiffs may bring Sherman Act claims for damages only if they plead and ultimately prove a causal connection between the challenged conduct (here, the ANDA Settlements), and the claimed antitrust injury (here, the alleged delay of Generic Namenda IR into the market). *See, e.g.*, *Balaklaw*, 14 F.3d at 797 n.9 (antitrust injury requires a "causal connection" between challenged conduct and the antitrust injury) (citing *AGC*, 459 U.S. at 537-45); *Lotes Co. v. Hon Hai Precision Indus. Co.*, 753 F.3d 395, 415 n.8 (2d Cir. 2014) ("[L]ack of causation in fact is fatal to the merits of any antitrust claim.") (internal quotation marks and citation omitted). Plaintiffs must therefore show that "the defendant's allegedly anticompetitive conduct was the actual and proximate cause" of Plaintiffs' antitrust injury. *In re Wellbutrin XL Antitrust Litig.*, Nos. 08-2431, 08-2433, 2015 WL 5582289, at *23, *24 (E.D. Pa. Sept. 23, 2015) ("Antitrust injury cannot be presumed simply because there is an agreement that results in harm.").

Plaintiffs claim that "but-for" the ANDA settlement agreements, generics would have entered earlier, either: (1) "at risk" after receiving FDA approval but before the patent litigation suit concluded[25]; (2) after litigating the patent infringement suits to completion and ultimately prevailing; or (3) by negotiating different settlement agreements with earlier entry dates. DPP ¶¶

[25] Plaintiffs allege that generics could have entered after the FDA's "30-month stay" began "to expire in or about April 2010." *See* DPP ¶ 107, 129-130; IPP ¶ 72, 80-81. But Plaintiffs are wrong: because Namenda received new chemical entity ("NCE") exclusivity, the FDA's stay was 7.5 years from Namenda's original approval date and therefore the FDA stay did not expire until *April 2011*. *See* 21 U.S.C. §§ 355(c)(3)(E)(ii), (j)(5)(F)(2). Therefore, absent an earlier (favorable) court decision, generics could not have entered at risk until April 2011 at the earliest.

9, 14, 131; IPP ¶ 81.[26] However, Plaintiffs' but-for scenarios are purely speculative and cannot support a reasonable inference of causation for at least the following reasons.

1. Plaintiffs Offer No Basis For The Allegation That Generics Would Have Entered At Risk

An "at risk" generic launch is so-named because in an at risk launch, a generic manufacturer enters the market after it receives FDA approval upon expiration of the 30-month stay of approval, but before patent litigation concludes, thus risking potentially enormous financial exposure if the patent ultimately is upheld, including potential treble damages and the brand's lost profits. *See* 35 U.S.C. § 284 (upon a finding of willful infringement "the court may increase the damages up to three times the amount found or assessed"). For example, two generic manufacturers recently agreed to pay $2.15 billion for selling a generic version of Protonix at risk, when the patent was later upheld. Peter Loftus, *Pfizer, Takeda to Get $2.15 Billion Settlement*, Wall Street Journal, June 12, 2013. And earlier this year, a generic manufacturer was ordered to pay $98.5 million in infringement damages for launching a generic version of Prilosec at risk. Final Judgment at 2, *Astrazeneca AB v. Apotex Corp.*, No. 01-cv-9351 (S.D.N.Y. June 30, 2015), ECF 280.

Given the potential for large infringement damages, it is far from a foregone conclusion that a generic manufacturer would choose to enter at risk before resolution of Paragraph IV litigation.[27] Therefore, plaintiffs must make specific allegations that the generics desired or intended to enter at risk before courts accept plaintiffs' theory that the generic would have

[26] DPPs also allege a fourth but-for world: absent the ANDA Settlements, generic Namenda IR would have launched in April 2015. This allegation, which misapplies the pediatric exclusivity regulations, is discussed below. *See infra* Section II.D.

[27] For example, between 2003 and 2009, out of 238 Paragraph IV litigations, there were only 23 instances (9.6%) where the generic chose to enter at risk. Adam Greene, *Analyzing Litigation Success Rates*, RBC Capital Markets (January 15, 2010), http://amlawdaily.typepad.com/pharmareport.pdf.

entered at risk. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 204-05 (E.D.N.Y. 2003) (rejecting Plaintiffs' theory of injury based upon theory that generic would have entered at risk, where no allegations that generic had the desire or intent to enter at risk).

Here, Plaintiffs provide no basis whatsoever to assume that—absent the ANDA Settlements—generics would have launched at risk. This "general theory of causation is too speculative to state an antitrust injury resulting from the settlement agreements," and the court should therefore reject it. *See Actos*, 2015 WL 5610752, at *26; *see also Iqbal*, 556 U.S. at 678 ("Threadbare recitals . . . supported by mere conclusory statements, do not suffice" to state a plausible claim); *AGC*, 459 U.S. at 543 (finding no injury where "nothing but speculation informs the [plaintiff's] claim of injury by reason of the alleged unlawful coercion").

2. Plaintiffs' Speculative Early Entry Date is Implausible in Light of Claim Construction Ruling Favoring Forest

Plaintiffs' next but-for world—hypothesizing that generics would have litigated the patent case to completion *and prevailed*—is the type of sheer speculation regarding litigation outcomes that courts routinely reject. *See Actos*, 2015 WL 5610752, at *27 ("assumptions regarding success at trial are generally rejected as unduly speculative"); *In re Cipro*, 261 F. Supp. 2d at 200-02 (E.D.N.Y. 2003) (dismissing as too speculative claims that "relie[d] on the hope" that the generic company would have succeeded in its patent litigation (citing *Whitmore v. Arkansas*, 495 U.S. 149, 159-160 (1990) (legal theory dependent on predicting outcome of specific lawsuit is unduly speculative))); *FTC v. AbbieVie Inc.*, No. 14-cv-5151, 2015 WL 2114380, at *8 (E.D. Pa. May 6, 2015) ("[A]llegations that the court would likely rule in favor of [one party] is merely speculation. No matter what someone's crystal ball may have supposedly revealed, the [court] had not held a trial, had not been presented with any evidence, and had not decided the matter.") (citations omitted).

Moreover, because the patent court had issued a claim construction decision that was unfavorable to generics, Plaintiffs' speculation that, but-for settlement, generics would have ultimately prevailed in the patent litigation is particularly implausible. The July 2009 claim construction report and recommendation repeatedly credited plaintiff Forest's proposed claim construction over generic defendants' proposed construction for the '703 patent, acknowledging "I have largely sided with Plaintiffs." Report & Recommendations Regarding Claim Construction at 21, *Forest Labs., Inc. v. Lupin Pharm.*, No. 08-021 (D. Del. July 2, 2009), ECF 373. Claim construction is often outcome determinative in patent infringement litigation. *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 540 (Fed. Cir. 1998) ("In this case, as often occurs, the question of literal infringement was resolved upon the court's construction of the claims.") (citing *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 999 (Fed. Cir. 1995) (Newman, J., dissenting) ("Deciding the meaning of the words used in the patent is often dispositive of the question of infringement.")). Therefore, it is unsurprising that on the heels of receiving an unfavorable claim construction report, the generics began to settle. Four generic manufacturers settled in September 2009, with agreements that allowed entry three months prior to patent and regulatory expiration. Notably, by agreeing to enter only three months before loss of exclusivity, these generics forewent three months of their 180-day exclusivity period, since the exclusivity period automatically expires when the drug loses patent and regulatory exclusivity. *See infra* Section II.E.

In September 2009, the court issued an order largely rejecting objections to the claim construction report of the remaining defendants, (Order, *Forest Labs., Inc. v. Lupin Pharm.*, No. 08-021 (D. Del. Sept. 21, 2009), ECF 426), leading to a second wave of settlements. Within weeks, two more generics settled, with four more generics settling shortly thereafter, and the

remaining two settling within a year of the claim construction decision. In the face of the fact that generic manufacturers chose to settle directly after receiving an unfavorable claim construction decision that greatly affected their chance of success in the patent litigation, Plaintiffs' allegation that the generics would have litigated to the bitter end, *and prevailed*, is implausible.

3. No Second-Guessing an Otherwise Procompetitive Settlement Agreement

Finally, Plaintiffs' argument that, but-for the ANDA Settlements, generics would have entered into different settlement agreements with earlier entry dates is unavailing, as it impermissibly second-guesses the ANDA Settlements. The ANDA Settlements are procompetitive in that they allow generic entry prior to expiration of patent and regulatory exclusivity. *Actavis*, 133. S.Ct. at 2234 ("[S]ettlement on terms permitting the patent challenger to enter the market before the patent expires would . . . bring about competition . . . to the consumer's benefit."). Plaintiffs cannot premise an antitrust theory on the claim that they could imagine a different agreement that might have been *even more* procompetitive. *Trinko*, 540 U.S. at 415-16 (antitrust laws cannot condemn an otherwise procompetitive course "whenever some other approach might yield greater competition"); *La. Wholesale Drug Co. v. Shire LLC*, 929 F. Supp. 2d 256, 262 (S.D.N.Y. 2013) ("The mere fact that pricing for the public *could have been lower* under the terms of a particular settlement agreement does not mean that an antitrust violation results when that theoretical optimal result for consumers is not met."); *aff'd In Re Adderall XR Antitrust Litig.*, 754 F.3d 128 (2d Cir. 2014); *In re Cipro*, 363 F. Supp. 2d at 536 (Settling parties "cannot be penalized just because plaintiffs can imagine a more pro-competitive settlement, if the agreement they did reach does not adversely affect competition . . . .").

4. No Causation Where Patent or Regulatory Scheme Prevented Entry

Plaintiffs allege that absent the settlement agreements, Generic Namenda IR would have entered the market significantly earlier. *See* DPP ¶¶ 9, 14, 131; IPP ¶ 81. However, Plaintiffs must allege that an earlier entry would have been *lawful*. If competition is precluded by an independent regulatory scheme, conduct by Defendants could not have caused an injury of the type that antitrust laws were designed to remedy. *See, e.g.*, *In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 791 (8th Cir. 2006); Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles & Their Application* ¶ 338b (4th Ed. 2015) (collecting cases) (plaintiffs lack antitrust injury where "a force other than the antitrust violation fully accounts for the plaintiff's injury."). In *Canadian Import*, the Eighth Circuit held that plaintiffs suffered no antitrust injury, where the alleged injury—increased prices due to plaintiffs' inability to import drugs from Canada—arose because federal law banned such importation, and the absence of competition was therefore caused by the statutory and regulatory schemes, not by defendants' conduct. *Id*.

Accordingly, courts have found that where a valid patent exists, the patent independently precludes competition apart from any agreement regarding generic entry, and therefore the patent cuts off the chain of causation necessary to establish antitrust injury. *See Wellbutrin XL*, 2015 WL 5582289, at *28 ("The existence of a valid . . . patent [disrupts a plaintiff's] chain of causation [because] a valid patent independently 'preclude[s] competition' apart from any agreement[,] and an 'at risk' launch is unlawful absent a later finding of patent invalidity or non-infringement.") (internal quotation marks omitted) (citing *City of Pittsburgh v. W. Penn. Power Co.*, 147 F.3d 256, 269 (3d Cir. 1998); *see also Wellbutrin*, 2015 WL 5582289, at *28 ("It was the patent itself, therefore, and not the [settlement agreements], that caused [the generic drug's]

lack of market presence."). Therefore, because generics were precluded from entering the market prior to the date of actual Generic Namenda IR entry due to Forest's lawful patent and regulatory exclusivity, Plaintiffs cannot allege that the ANDA Settlements caused harm to competition.

C. Commonplace Business Agreements Between Forest And Two Other Generic Manufacturers Cannot Constitute Unlawful Reverse Payments Under *Actavis*

Forest's business agreements with Mylan and Orchid—two generic manufacturers that are not named as defendants in these cases—also present no reverse payment concerns.[28] *Actavis* made clear that "traditional" or "commonplace" agreements, such as those that transfer value in exchange for goods or services, are something "quite different" than reverse payment settlements in which the patentee is paying money to the generic "simply so it will stay away from the patentee's market." *Actavis*, 133 S. Ct. at 2233. These business agreements, in which Forest (1) amended a distribution agreement with Mylan related to an authorized generic product (KO Decl. Ex. 15), and (2) entered a development and supply agreement with Orchid for a new drug (KO Decl. Ex. 12), are commonplace in the pharmaceutical industry, and therefore raise no antitrust concerns under *Actavis*. Indeed, Plaintiffs make no allegations whatsoever regarding these business agreements, let alone that they constitute reverse payments under *Actavis*[29]; nor could Plaintiffs make such allegations because the agreements are routine, mutually beneficial business agreements that do not contain reverse payments made in consideration for generic delay.

[28] Merz is not party to either agreement.

[29] Pursuant to the Court's order, the Plaintiffs received the agreements with Mylan and Orchid on November 23, 2015. Plaintiffs have not sought to amend their complaints to assert any claims regarding these agreements.

1. The Mylan Amendment Contained No Reverse Payment

The Mylan Amendment is an amendment to a 2005 distribution and supply agreement between Forest and Alphapharm (later acquired by Mylan) (KO Decl. Ex. 14), in which Forest licensed Alphapharm to be the exclusive distributor of the authorized generic version of Forest's Lexapro drug. The Mylan Amendment was designed to restructure the relationship following Mylan's acquisition of Alphapharm for the mutual benefit of both business partners by assigning the formal distribution rights from Alphapharm to Mylan, and by relieving Forest of its duty to manufacture and supply the authorized generic product. KO Decl. Ex. 15 §§ 1.1, 5.1.

Mylan undertook a number of significant obligations in the Mylan Amendment. For example, Mylan agreed to [redacted] KO Decl. Ex. 15 § 4. Mylan further agreed to be [redacted] *Id.* § 5.1. The [redacted] *Id.* Mylan represented [redacted] *Id.* § 7.1. Mylan further undertook responsibility to [redacted] *Id.* § 7.1. [redacted].[30] *Id.* § 8.4. In consideration for Mylan taking over manufacturing responsibility and

[30] "Generally speaking, it is the responsibility of a drug manufacturing-processing company to comply with the current CGMP regulations and the provisions of the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq*." *United States v. Richlyn Labs., Inc.*, 827 F. Supp. 1145, 1149 (E.D.

for bearing the costs to have an appropriate manufacturing facility qualified by the FDA, the Mylan Amendment provided for payment of $[redacted] to Mylan. *Id.* § 6.1. [redacted] *Id.* § 6.2.

The Mylan Amendment was therefore a routine, mutually beneficial business agreement, in which Forest invested in Mylan in order to reduce the costs and burdens associated with its manufacturing responsibilities under the original Alphapharm agreement. Any value exchanged as part of the Mylan Amendment is the type of traditional consideration reflecting fair value for services that is not an actionable reverse payment under *Actavis* in the first place. *See Actavis*, 133 S. Ct. at 2236 ("Where a reverse payment reflects traditional settlement considerations, such as . . . fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.").

2. The Orchid Supply Agreement Contained No Reverse Payment

The Orchid Supply Agreement (embodied in a binding term sheet) is an agreement for the development and supply of the drug [redacted]. Pursuant to the multi-phase agreement, Orchid was to manufacture development batches of API (active pharmaceutical ingredient) for [redacted] over a period of [redacted] months, which would undergo stability testing and be used to qualify Orchid as a manufacturer of [redacted] API in Forest's regulatory filings. KO Decl. Ex. 12 § 3. Orchid would then manufacture validation batches of the API once registration for [redacted] as a new chemical entity was filed, in accordance to specification. *Id.* § 4. Finally, once regulatory approvals were obtained, Forest would purchase commercial batches of API

Pa. 1992). The provisions in the Mylan Amendment implicate dozens of federal regulations. *See, e.g.,* 21 C.F.R. § 211, *et seq.* (enumerating numerous regulations relating to good manufacturing practices for finished pharmaceuticals).

from Orchid. *Id.* § 4. Under the agreement Forest would make payments to Orchid upon completion of the various phases. *Id.* § 6.

No "Large and Unjustified" Payment. The Orchid Supply Agreement provides for only a $[redacted] initial payment, and up to $[redacted] additional payments for development and consulting contingent upon Orchid's achievement of milestones. *Id.* § 6. Not only are these payments not "large," they are fully justified as "compensation for other services that the generic has promised to perform." *Actavis*, 133 S. Ct. at 2236; *see also HealthPro Bioventures, LLC v. Prometic Life Scis. Inc.*, No. 10-cv-3295, 2011 WL 5419706, at *10 (S.D.N.Y. Nov. 8, 2011) (milestone payments generally understood to be payments earned through performance of future events). The payments are thus only payable upon Orchid's achievement of manufacturing and consulting milestones that confer benefit to Forest, and Orchid's failure to perform milestone services as required is cause for termination of the agreement. KO Decl. Ex. 12 § 10; *see also Breckenridge Pharm., Inc. v. Midland Healthcare, LLC*, No. 07-cv-11114, 2008 WL 3833780, at *4-6 (S.D.N.Y. Aug. 11, 2008) (failure to render milestone services is grounds for breach of contract and may require the receiving party to reimburse milestone sums paid under the agreement).

Under the Orchid Supply Agreement, Orchid would disclose to Forest all optimization and cost-saving processes identified in the development and manufacture of [redacted], a new antibiotic. KO Decl. Ex. 12 § 6. Orchid further agreed that Forest would own or be assigned all intellectual property, including but not limited to, patents covering the manufacture or development of [redacted], regardless of whether developed by Forest or Orchid. *Id.* § 8. The intellectual property and know-how provided by Orchid under the agreement is value flowing to

Forest. The small payment to Orchid—subtracted by the value provided to Forest—simply is not a large and unjustified reverse payment on the face of the agreement.

D. Settlement Provided for Early Entry Before Exclusivity Expired: Plaintiffs Cannot Allege Delay Beyond Expiration Of Patent And Regulatory Exclusivity

DPPs allege that Forest improperly extended its patent monopoly because the challenged settlement agreements did not permit generic entry prior to the start of Forest's pediatric exclusivity period. DPP ¶¶ 251-257. As far as Forest is aware, DPPs' theory has ***never*** been argued in an antitrust case—let alone accepted. This is for good reason. DPPs' theory is premised on a misunderstanding of the interplay of the pediatric exclusivity statute and Hatch-Waxman. Forest earned six additional months of regulatory exclusivity by conducting costly pediatric studies for the treatment of autistic children, at the FDA's request. When settling their patent disputes, Forest and the generic firms properly accounted for the possibility of a pediatric exclusivity period in negotiating the generics' early entry dates. DPPs suggest that those settlements were somehow anticompetitive because pediatric exclusivity attaches only to certain ANDAs and did not attach to the ANDAs at issue here. DPPs are wrong. Pediatric exclusivity attached to Forest's *'703 patent*. Consequently here, had the generic firms lost the '703 patent infringement suits, FDA would not have permitted those generics to launch their products until the expiration of Forest's earned pediatric exclusivity period—October 11, 2015.

1. FDA Approval of Any Memantine IR ANDA Was Subject to Forest's Earned Pediatric Exclusivity Period

a. Congress Created Pediatric Exclusivity to Incentivize Innovator Pharmaceutical Companies to Conduct Costly Pediatric Clinical Trials

Congress created the six-month pediatric exclusivity period as an incentive for innovator pharmaceutical companies to conduct costly pediatric clinical trials. Congress was aware that

this regulatory exclusivity period would mean that generic drugs may enter the market later than they would have in the absence of this period. *See* S. Rep. No. 105-43, at 52, 73 (1997); H.R. Rep. No. 107-277, at 28-29 (2001); S. Rep. No. 107-79, at 11 (2001). Yet, after balancing the various interests, Congress made a conscious policy decision to award six-months of exclusivity to pharmaceutical companies that complete pediatric studies according to FDA requirements.

Not all drugs receive pediatric exclusivity. A drug is eligible for pediatric exclusivity only after a series of well-regulated steps have been completed. *First*, the FDA must issue a written request for pediatric studies from a NDA holder. *See* 21 U.S.C. § 355a(c)(1).[31] *Second*, after receiving a written request, the NDA holder must conduct those clinical trials in complete accordance with the FDA's request. *See* 21 U.S.C. § 355a(d)(3). *Third*, once completed, the NDA holder must submit a report of the studies' conclusions to the FDA. *See id.* *Lastly*, if the FDA determines that the report satisfies various conditions, such as use of commonly accepted scientific principles and protocols, the FDA will accept it. *See* 21 U.S.C. § 355a(d)(3).

b. Pediatric Exclusivity Applied Here Because the FDA's Pediatric Exclusivity Determination Was Timely

By Congressional design, pediatric exclusivity attaches to any existing periods of regulatory exclusivity and any Orange Book-listed patents for the relevant drug product. 21 U.S.C. §§ 355a(b), (c). Both new and already-marketed drugs are eligible for pediatric exclusivity. Once a drug is eligible for pediatric exclusivity, existing periods of regulatory and patent exclusivity are extended by six-months according to the terms of the statute. 21 U.S.C.

[31] In the interest of efficiency, Sponsors may propose pediatric studies and suggest that the FDA issue a written request. In fact, the "FDA encourages applicants to make such proposals." FDA, *Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act: Frequently Asked Questions on Pediatric Exclusivity (505A), The Pediatric 'Rule,' and their Interaction.* Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm077915.htm. Such proposals, however, are not a guarantee. Whether a request issues is entirely within the FDA's discretion.

§§355a(b), (c). All ANDAs are potentially subject to an innovator's pediatric exclusivity period. The FDA submitted its written request with respect to Namenda IR in January 2012, asking Forest to study Namenda IR in autistic children. *See Namenda I*, 2014 WL 7015198, at *11. Forest incurred costs of approximately $70 million to conduct its clinical trials examining the potential for treating autistic children with Namenda. *See id*. Because Forest completed the requested studies satisfactorily, the FDA granted Forest pediatric exclusivity, which Forest announced on June 18, 2014. *See id.* As of the FDA grant, pediatric exclusivity attached to Forest's '703 patent, and the FDA amended its Orange Book to reflect that the '703 patent was subject to pediatric exclusivity. KO Decl. Ex. 16.[32]

2. The Challenged Settlements Allowed Generic Challengers to Enter the Market Prior to the Expiration of Forest's Pediatric Exclusivity Period and Are Therefore Procompetitive

a. Forest Had a Legal Right to Exclude Competitors Based on Its Pediatric Exclusivity Period in Addition to Its Patent Rights

DPPs allege that "it is black letter patent law that a patentee's attempt to restrict the use of the invention beyond the expiration of the patent would be unenforceable and unlawful *per se*." DPP ¶ 128. In support of this argument, DPPs cite *Brulotte v. Thys Co.*, 379 U.S. 29 (1964) and its progeny, including *Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401 (2015). DPP ¶ 126. This argument misses the point and has no bearing on FDA's enforcement of Forest's pediatric exclusivity here. *Brulotte* and *Kimble* addressed whether a patentee could collect royalties post-patent expiration, but Forest did not collect royalties from any of the settling generics at all,

[32] Pediatric exclusivity applies to an Orange Book-listed patent *unless* the FDA determines that the NDA holder is eligible for pediatric exclusivity *less than nine months* prior to the expiration of that patent. 21 U.S.C. § 355a(b)(2), (c)(2). This exception does not apply here because pediatric exclusivity was granted in June 2014, more than nine months before patent expiry on April 11, 2015. DPPs do not and cannot allege that the FDA's grant of pediatric exclusivity for Namenda was untimely.

including during any portion of the pediatric exclusivity period. The challenged settlements therefore do not run afoul of the *Brulotte* and *Kimble* decisions.[33]

Moreover, Forest's lawful rights to exclude competitors from the Namenda market were not limited to its '703 patent. Forest had additional statutory rights to pediatric and other periods of regulatory exclusivity. The Federal Circuit recently addressed this issue in *AstraZeneca AB v. Apotex Corp*., 782 F.3d 1324 (Fed. Cir. 2015). In *AstraZeneca*, the Federal Circuit found that *Brulotte* does not control the outcome of a case concerning pediatric exclusivity beyond the term of a patent. *Id.* at 1342 ("The Court's analysis in *Brulotte*, however, does not apply to a situation such as this one, in which Congress, by creating the pediatric exclusivity period, explicitly authorized additional market exclusivity to be granted to the patent owner beyond the life of the patent."). Indeed, with pediatric exclusivity, a patentee's right to exclude competitors from the market "does not rest on its patent monopoly," it is drawn from the innovator company's "legal entitlement to a pediatric exclusivity period." *Id.*[34]

b. The Challenged Settlements Provided for "Early Entry" and Waiver of Regulatory Exclusivities and Are Therefore Lawful

Had the patent cases gone to trial and Forest prevailed, the relevant Hatch Waxman statutes would have enjoined the generics from entering until October 11, 2015. 35 U.S.C. § 271(e)(4)(A). Under most of the settlement agreements, Forest granted an "early entry" license to each first-filer generic challenger and waivers of regulatory exclusivities permitting the

[33] DPPs cite *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 2012 U.S. Dist. Lexis 79166 (D.N.J. June 7, 2012), which also addressed a patentee's ability to collect royalties during the pediatric exclusivity period, and not FDA's enforcement of the pediatric exclusivity period. DPP ¶ 122, 123. As with *Brulotte*, *Altana* is inapplicable here.

[34] DPPs admit this in their Complaint. *See, e.g.*, DPP ¶ 79, n.20 ("Such [generic drug manufacturers] must . . . wait for expiration of any applicable regulatory exclusivities . . . .").

generic to market its product at least three months *earlier*—July 11, 2015.[35] The challenged settlement agreements, which permitted entry before the expiration of the '703 patent and its pediatric exclusivity period, are traditional forms of settlement and therefore lawful under *Actavis*. *See Actavis*, 133 S. Ct. at 2233-36; *AstraZeneca*, 782 F.3d at 1342.

3. DPPs' Unprecedented Pediatric Exclusivity Theory Is Fatally Flawed and Cannot Save Its Complaint

DPPs argue that the challenged patent settlement agreements, in which Forest agreed to waive a certain period of its patent *and* FDA-granted pediatric exclusivity, improperly precluded generic competition for three months ***beyond*** the expiration of the '703 patent "because pediatric exclusivity did not extend the patent term with respect to the subject generic challengers," and therefore "but for" the settlement, Generic Namenda IR entry would have occurred on April 11, 2015. DPP ¶¶ 122, 129-130, 252. There is simply no "but for" scenario in which the generic challengers could have launched their products on April 11, 2015 without overcoming Forest's '703 patent.

a. Pediatric Exclusivity Affects the Potential FDA Approval Date of All ANDA Filers, Including Those Who File or Maintain a Paragraph IV Certification

DPPs argue that, under 21 U.S.C. § 355a(b)(1)(B)(ii) ("Section (B)(ii)"), Forest could not avail itself of its Congressionally-mandated pediatric exclusivity period because pediatric exclusivity somehow did not "attach" to the subject ANDAs. DPP ¶¶ 123-129. But pediatric exclusivity does not attach to certain ANDAs to the exclusion of others. Section (B)(ii) is merely part of a larger statutory framework which informs when the FDA can grant final approval to ANDAs.

[35] As discussed above, Apotex and Torrent received licenses to enter on October 11, 2015, the end of the exclusivity period. *See supra* Factual Background.

Because the '703 patent was listed in the Orange Book for Namenda, ANDA applicants were required to file one of three patent certifications with their ANDAs. 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12). If a generic firm decided not to challenge Forest's '703 patent (*i.e.*, by filing a Paragraph III certification as to the '703 patent's expiration date), it is undisputed that FDA could not have approved the ANDA until on or after October 11, 2015. 21 U.S.C. § 355a(b)(1)(B)(i)(II). Or if a generic firm had filed its ANDA after the '703 patent had expired but prior to the expiration of the pediatric exclusivity period (*i.e.*, by filing a Paragraph II certification that the '703 patent had expired), the FDA also could not have approved the ANDA until the expiration of the pediatric exclusivity period on October 11, 2015. 21 U.S.C. § 355a(b)(1)(B)(i)(I).

The ***only*** scenario in which a generic firm could avoid FDA's enforcement of Forest's pediatric exclusivity period, would have been to file a Paragraph IV certification and win the '703 patent litigation.[36] If Forest had prevailed in the patent litigation, the FDA could have approved the ANDAs no earlier than October 11, 2015. Indeed, 35 U.S.C. § 271(e)(4)(A) provides an automatic injunction to patentees who are successful in Hatch-Waxman litigation and when the FDA has determined that the NDA holder, like Forest here, is eligible for pediatric exclusivity, Section (B)(ii) extends by six months the date on which a generic firm can obtain approval for its Paragraph IV ANDA.[37] Here, there is no dispute that if the generic firms had not

[36] Because the FDA does not undertake any independent patent analysis, the FDA can, under certain circumstances, approve a Paragraph IV ANDA before the certified patent expires. First, if the innovator pharmaceutical company does not sue the generic firm for infringement within 45 days of receiving its Paragraph IV notice letter, the FDA can approve the ANDA "immediately." 21 U.S.C. 355(j)(5)(B)(ii). Second, if the generic firm ultimately prevails in the patent infringement litigation, the FDA can make ANDA approval effective on the date of the court decision. *Id.*

[37] Section (B)(ii) references 21 U.S.C. 355(j)(5)(B), which, as discussed *infra*, more generally addresses the dates on which FDA can approve ANDAs, including Paragraph IV ANDAs.

settled, requiring Forest to litigate the '703 patent infringement suits to a successful completion, the FDA could *not* have granted final approval to any memantine IR ANDAs until at least the expiration of the '703 patent *and* the associated pediatric exclusivity: October 11, 2015. 35 U.S.C. § 271(e)(4)(A); 21 U.S.C. § 355a(b)(1)(B)(ii).

b. A Court Decision on Infringement and Validity of the '703 Patent Was Not Required for Pediatric Exclusivity to Apply to the Memantine IR Paragraph IV ANDAs

Forest's '703 patent was statutorily presumed to be valid and enforceable. 35 U.S.C. § 282. No Paragraph IV ANDA filer ever overcame that presumption, and DPPs have provided no evidence to suggest that any of the more than fifteen generic firms could have won its '703 patent case. *See supra* Section II.B.2. The fact that a district court did not rule on the validity and infringement of Forest's '703 patent does not alter this result. Forest did not forfeit its pediatric exclusivity period associated with the '703 patent by settling its patent disputes. A patentee can enforce its pediatric exclusivity period in the absence of such a court decision. *In re Omeprazole Patent Litigation*, 490 F. Supp. 2d 368, 378 (S.D.N.Y. 2007), *aff'd* 536 F.3d 1361 (Fed. Cir. 2008). In *Omeprazole*, Impax argued that the Court was "powerless to enforce the period of pediatric exclusivity because section 355a requires a 'court determin[ation] that the patent is valid and would be infringed' in order for the ANDA with a Paragraph IV certification to be subject to the period of pediatric exclusivity." *Id. at* 378. The court rejected this argument: "Simply because the statutory provisions do not address the specific fact pattern before us does not mean that Astra is not entitled to the six-month period of market exclusivity that it earned by conducting the requested pediatric studies." *Id.* Indeed, the Court found "Impax's interpretation of the statutory provisions would create an anomalous result that is at odds with Congress's goal in enacting § 355a." *Id.* at 379. And that is the right result. Otherwise, generic applicants would

eviscerate every pediatric exclusivity period with too-late-to-be-resolved Paragraph IV challenges.

c. The District Court Orders Acknowledged Forest's Rights to Exclude Through Pediatric Exclusivity

DPPs contend that because "all of the Potential First-Filing Generics maintained Paragraph IV certifications to the '703 Patent despite the settlement of the patent lawsuits," pediatric exclusivity did not attach to the '703 patent. DPP ¶ 129. DPPs' theory could only make sense if the "first filer" generic challengers had actually won the patent litigation.

Here, given that the generic challengers did not prevail in the patent suits, they could only maintain their Paragraph IV certifications, and therefore launch their products prior to the expiration of the pediatric exclusivity period associated with the '703 patent, under the terms of their licenses from Forest.[38] This result was ordered by the district court. As part of the challenged settlement agreements, the district court entered stipulated orders dismissing the litigation between Forest and each generic challenger. Each court order "enjoined [the generic challengers] from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, the generic tablet products containing 5 milligrams or 10 milligrams of memantine hydrochloride per tablet that are the subject of [this ANDA] during the life of the '703 Patent, ***including any extensions and pediatric exclusivities***, absent a license agreement or other authorization by Plaintiffs[.]" KO Decl. Exs. 1-11; 13 (emphasis added). As a result, to the extent that the generics could have launched their products earlier than October 11, 2015, it was only in accordance with the controlling court orders.

[38] *See Barr Labs., Inc. v. Thompson*, 238 F. Supp. 2d 236, 242-43, 253 (D.D.C. 2002) (holding FDA properly refused to allow Barr to market generic tamoxifen citrate product until expiry of pediatric exclusivity where Barr converted Paragraph IV certification to Paragraph III certification as part of settlement agreement with AstraZeneca).

4. DPPs' Pediatric Exclusivity Theory, if Adopted, Would Undermine the Strong Public Interests in Encouraging Settlement of Patent Disputes and Medical Research in the Pediatric Population

Under DPPs' theory of the case, Forest's statutory rights to its regulatory exclusivity periods were necessarily destroyed by any settlement. DPPs provide no support whatsoever for such an anomalous and punitive result. Indeed, if DPPs are correct that an innovator necessarily relinquishes its statutory right to pediatric exclusivity anytime it settles a Hatch-Waxman patent infringement suit, no such cases could settle amid fears that they too would be susceptible to the same type of antitrust challenge. But encouraging settlement, including in the patent context, is an important public and institutional policy for the courts.[39]

Even worse, innovators would be discouraged from pursuing costly and time-consuming studies in pediatric patients. Any innovator who had settled—or hoped to settle—its Hatch-Waxman patent litigation would be reluctant to agree to any FDA requests to conduct expensive pediatric trials. DPPs here seek to punish Forest for conducting clinical trials and being granted pediatric exclusivity. DPPs allege that the challenged settlement agreements, pursuant to which Forest granted an early entry license to each generic challenger and waivers of regulatory exclusivities permitting it to market its product at least three months *early*, somehow became unlawful once Forest earned pediatric exclusivity for its '703 patent and the generics' early entry dates shifted accordingly. If DPPs are permitted to pursue their novel theory, it would destroy the incentive to conduct pediatric studies that Congress created almost twenty years ago.

[39] *See Bano v. Union Carbide Corp.* 273 F.3d 120,129-30 (2d Cir. 2001) ("it is axiomatic that the law encourages settlement of disputes" and explaining that if the court were to allow action covered by previous settlement agreement to proceed then the court would "fail to vindicate the reasonable expectations of [the defendant]" and "also risk undermining the ability of defendants generally to gauge in advance the finality of settlements . . . .").

E. The ANDA Settlement Agreements Do Not Create An Impermissible Bottleneck

DPPs allege that the challenged settlement agreements "served as a 'cork in the bottle'," and "prevented any generic other than the Potential First-Filing Generics from entering the marketing until 180 days after July 2015." DPP ¶ 140. DPPs are wrong. The challenged settlement agreements could not delay entry for any subsequent ANDA filers because any 180-day first-filer generic exclusivity period necessarily terminated upon the expiration of the '703 patent and its associated pediatric exclusivity on October 11, 2015.

The 180 days of exclusivity provided to first-filer generic manufacturers only prevents the FDA from approving other non-first filer Paragraph IV applicants. 21 U.S.C. § 355(j)(5)(B)(iv). After a patent expires, Paragraph IV certifications are no longer valid. 21 U.S.C. § 355(j)(2)(A)(vii)(II), (IV); *see also Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 357 (D.N.J. 2003). Therefore, once the patent and related exclusivity period expires, generic exclusivity no longer prevents the FDA from approving second-filers' applications.

The challenged settlement agreements therefore could not create a "cork in the bottle" due to first-filer generic exclusivity as DPPs suggest. The law simply does not allow it. Once the '703 patent and its associated pediatric exclusivity period expired, the FDA was no longer hindered by any generic 180-day exclusivity period because, at that time, Paragraph IV ANDAs (the only type of ANDA affected by the 180-day exclusivity period) no longer existed. Therefore, upon expiration of the pediatric exclusivity period, the FDA was free to approve any ANDA.

That is exactly how the FDA enforced its statutory mandate here. For example, under its license from Forest, Torrent (a second filer) could launch its product no later than the expiration of the '703 patent, including any patent term extension and/or pediatric exclusivity period,

subject only to Torrent obtaining final ANDA approval from the FDA. KO Decl. Ex. 9 § 1.11. Thus, the only impediment to Torrent launching its product immediately after the pediatric exclusivity period expired was its ability to obtain FDA approval. The FDA, in properly implementing the Hatch-Waxman regime, began granting final approval to second filers, including Torrent, immediately upon the expiration of the pediatric exclusivity period.[40] Forest's settlement agreements with the first filers did not create a bottleneck for Torrent. Therefore, DPPs' "bottleneck" allegation is simply wrong.

III. PLAINTIFFS FAIL TO ALLEGE AN OVERARCHING CONSPIRACY OR SCHEME

A. Plaintiffs Fail To Plausibly Allege Conspiracy With Generics

Although Plaintiffs try to allege that Forest engaged in an overarching conspiracy between and among all of the settling generic manufacturers to enter unlawful ANDA Settlements in order to delay entry of Generic Namenda IR, Plaintiffs' allegations fall far short of a plausible conspiracy claim. To assert a claim for conspiracy, "an allegation of parallel conduct and a bare assertion of conspiracy will not suffice." *Twombly*, 550 U.S. at 556-57; *see also id.* at 554 (parallel conduct could simply be result of "wide swath of rational and competitive business strategy unilaterally prompted by common perceptions of the market"). Plaintiffs therefore must allege enough facts to suggest that Defendants and generic manufacturers entered into an actual *agreement* to conspire. *See id.* at 556-57 ("Without more, parallel conduct does not suggest conspiracy, and a conclusory allegation of agreement at some unidentified point does not supply facts adequate to show illegality."). Yet, all Plaintiffs allege is that the ANDA Settlements have

[40] Torrent obtained final approval for its ANDA on October 13, 2015, the first business day after the '703 patent's pediatric exclusivity period expired. Memantine Hydrochloride by Torrent Label and Approval History, FDA Approved Drug Products, (updated Dec. 21, 2015), http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist.

identical entry dates (DPP ¶ 117; IPP ¶ 77-79)—and even that allegation is false. *E.g.*, *compare* KO Decl. Ex. 1 § 1.14 (entry date three months prior to '703 patent expiration), *with* KO Decl. Ex. 3 § 1.14 (entry date on expiration of the '703 patent).

As set out more fully in the Generic Defendants' brief, Plaintiffs fail to plausibly allege any evidence—either direct or circumstantial—supporting an inference of conspiracy. *See* Brief of Generic Defendants ("Generic Br.") at 20-31.

Plaintiffs further allege an overarching conspiracy in which Defendants delayed Generic Namenda IR entry into the market in order to allow Forest to implement a "hard switch." As set out more fully in the Generic Defendants' brief, Plaintiffs fail to advance *any* theory, let alone a plausible one, in which the settling generics would agree to delay their *own entry* to benefit their competitor Forest. *See* Generic Br. at 20.

Accordingly, Plaintiffs' implausible and barren allegations of an "overarching conspiracy" should be rejected.

B. Plaintiffs Cannot Revive Two Implausible Theories By Rebundling Them As An Overarching Scheme To Monopolize

Plaintiffs also attempt to lump their product hopping and ANDA Settlement claims together into a claim for an "overarching scheme" to monopolize, alleging that Forest unlawfully delayed entry of Generic Namenda IR, which enabled Forest to implement a hard switch. *See* DPP ¶ 243; IPP ¶¶ 193-195. But both of these claims individually fail: there was nothing unlawful about the ANDA Settlements (*see supra* Section II.B.), and Forest did not unlawfully convert the market to Namenda XR (*see supra* Section I.B). Plaintiffs cannot create a plausible claim by joining two inadequate allegations because, as the Supreme Court has recognized: "Two wrong claims do not make one that is right." *LinkLine*, 555 U.S. at457; *see also AbbieVie Inc.*, 2015 WL 2114380, at *7. The Second Circuit similarly has recognized that where "alleged

instances of misconduct are not independently anti-competitive . . . they are not cumulatively anti-competitive either." *Eatoni Ergonomics, Inc. v. Research in Motion Corp.*, 486 F. App'x 186, 191 (2d Cir. 2012); *see also Ne. Tel. Co. v. AT&T*, 651 F.2d 76, 95 n.28 (2d Cir. 1981); *City of Groton v. Conn. Light & Power Co.*, 662 F.2d 921, 928-29 (2d Cir. 1981); *cf. Am. Floral Servs., Inc. v. Florists' Transworld Delivery Ass'n*, 633 F. Supp. 201, 216 n.23 (N.D. Ill. 1986) ("zero plus zero plus zero still equals zero . . . . If no incident has probative value, all incidents taken together have no probative value."). Accordingly, Plaintiffs cannot breathe new life into their independently unsuccessful claims by simply labeling them an "overarching scheme."

IV. DPPS' CLAIMS ARE TIME-BARRED BY THE STATUTE OF LIMITATIONS

A. The Limitations Period Expired Before These Actions were Commenced

DPPs' claims are time barred because DPP's original Complaint was filed on September 22, 2015, more than five years after the last settlement agreement was executed. An antitrust cause of action accrues "when a defendant commits an act that injures a plaintiff's business." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 338 (1971). Plaintiffs allege injury in the form of increased prices for Namenda due to delayed Generic Namenda IR entry resulting from the ANDA Settlements. DPP ¶¶ 15-17. Because the last ANDA Settlement was entered on July 21, 2010, Plaintiffs' alleged causes of actions accrued on that date or earlier. *See* DPP ¶¶ 15-17 (alleging first of ANDA Settlements was entered on September 1, 2009, the last on July 21, 2010); *see also* DPP ¶ 113; KO Decl. Exs. 1-11,13.

Accordingly, DPPs' claims are time-barred by the four-year limitations period in the Sherman Act and should be dismissed. 15 U.S.C. § 15b.[41]

[41] Should the Court disagree, at the very least it should limit IPPs' damages to four years prior to the filing of their Complaint—August 19, 2011, as opposed to the damages period asserted by IPPs as of April 14, 2010. *See* IPP ¶ 146.

B. Plaintiffs Fail To Show Any Continuing Violation To Justify Extending The Limitations Period

DPPs do not allege fraudulent concealment, nor could they because the material terms of the ANDA Settlements were publicly announced between November 9, 2009 and July 22, 2010, as DPPs acknowledge. *See* DPP ¶ 118 n.23 (listing publicly available sources announcing the agreements). DPPs also cannot save their claims by alleging that the anti-competitive effects of the ANDA Settlements continued past the accrual dates (*see* DPP ¶ 193), because DPPs do not allege any continuing ***conduct*** by Defendants, and thus resetting the statute of limitations would be wholly improper.

To the extent DPPs intend to rely on the continuing payment of alleged supra-competitive prices to toll the limitations period, the Second Circuit has explicitly rejected that theory. *United States v. Grimm*, held that a "conspiracy ends notwithstanding the receipt of anticipated profits" where payments are merely a lengthy "series of ordinary, typically noncriminal, unilateral actions . . . *and* there is no evidence that any concerted activity posing the special societal dangers of conspiracy is still taking place." 738 F.3d 498, 502 (2d Cir. 2013). In *Grimm*, the defendants were convicted for conspiring to rig bids for municipality contracts to artificially deflate interest rates. *Id*. at 503. The contracts challenged were entered into five years prior to the government's indictment, but the DOJ contended that because victims were forced to pay "fixed" interest rates within the limitations period, that limitations period was refreshed every single time interest rates were paid. *Id*. at 503, 508. The Second Circuit rejected that argument, holding that the mere receipt of continuing payments resulting from the conspiracy "is not continuous action that prolongs the life of the conspiracy." *Id*. at 504. "Though the result of the conspiracy may be continuing, the conspiracy does not thereby become a continuing one." *Id.*

Although *Grimm* was a criminal case, its rule of law was applied in parallel antitrust civil

actions. *See Hinds Cnty. v. Wachovia Bank N.A.*, 620 F. Supp. 2d 499, 519-20, 522 (S.D.N.Y. 2009); *Hinds Cnty. v. Wachovia Bank N.A.*, 811 F. Supp. 2d 910, 914 (S.D.N.Y. 2011).

In *In re Ciprofloxacin Antitrust Litig.*, the court, presented with nearly identical allegations of illegal reverse payments rejected the argument that continued adherence to the "fixed terms of the challenged agreements" extended the statute of limitations. 261 F. Supp. 2d at 212, 219, 229-30. Other Circuit courts have required active *conduct* by defendants to justify restarting statutes of limitations, and have refused to allow indefinite resets where plaintiffs, including those claiming overcharges, challenge a discrete event. *See Grand Rapids Plastics, Inc. v. Lakian*, 188 F.3d 401, 406 (6th Cir. 1999) ("individual payments…were only a manifestation of the previous agreement . . . . [and] therefore do not constitute a 'new and independent act,' as required to restart the statute of limitations"); *Kaiser Aluminum & Chem. Sales, Inc. v. Avondale Shipyards, Inc.*, 677 F.2d 1045, 1053, 1056 (5th Cir. 1982) (receipt of benefits under fixed contract "were merely 'the abatable but unabated inertial consequences of some pre-limitations action'").

Berkey Photo is in accord. *Berkey Photo* held that where damages are speculative at the time of the conduct a plaintiff could rely on anticompetitive conduct from outside the limitations period to support a claim for monopolization. 603 F.2d at 295 (expressing concern with recovery of speculative damages); *see also* Areeda & Hovenkamp ¶ 320c4 (*Berkey Photo* should be understood in light of its "limiting language" concerning speculative damages). But DPPs allege that their claims became entirely non-speculative when the FDA approved Dr. Reddy's ANDA for Namenda on April 14, 2010—more than five years before the Complaints in this case were filed because but for the settlements Generic Namenda would have entered the market at that time. DPP ¶¶ 133, 136; IPP ¶¶ 72, 83, 146. DPPs also allege the certainty of generic

erosion: "Once a generic equivalent hits the market, the generic quickly captures sales of the corresponding brand drug, often capturing 80% or more of the brand's sales in the first six months." DPP ¶ 46. Moreover, *Berkey Photo* involved *conduct*, not just continuing payment, in the limitations period. 603 F.2d at 293-94 (describing continuing exclusionary conduct in the limitations period, not merely overcharges). Therefore, *Berkey Photo* does not change the fact that Plaintiffs' claims are time-barred, and as such, DPPs' claims must be dismissed.

C. The Statute Of Limitations Cannot Be Tolled By A "Hard Switch" That Never Occurred

Plaintiffs' "hard switch" allegation that Defendants engaged in an illegal product hopping scheme (*see* DPP ¶¶ 143-186, 238, 246.c., 260; IPP ¶¶ 87-139, 195) does not act to toll the limitations period. Forest never actually removed Namenda IR from the market, and was prohibited from doing so by a court ordered injunction. *See, supra* Section I.A.2. Without any actual removal of Namenda IR from the market, Plaintiffs can allege no anti-competitive acts that would extend the accrual date.[42]

V. IPPs' CLAIMS FAIL FOR ADDITIONAL REASONS UNDER INDIVIDUAL STATE LAWS

A. IPPs Lack Standing Under The Laws Of Several States

1. IPPs Lack Article III Standing to Assert Claims Under the Laws of States Where They Fail to Allege Injury

As discussed more fully in the Generic Defendants' brief, IPPs lack standing to bring claims under the laws of states in which they do not—and cannot—claim to have been injured. IPPs claim to have purchased Namenda in only 11 states: California, Delaware, Florida,

[42] Similarly, the antitrust laws of 26 states alleged by IPPs, the consumer protection laws of 21 states alleged by IPPs, and the unjust enrichment claims of 28 states alleged by IPPs have limitations periods of five years or less (*see* Appendices 2-4), making it likely that these claims are also time-barred.

Georgia, Kansas, Nevada, New Jersey, New York, Pennsylvania, South Carolina, and Virginia.[43] IPP ¶ 15. Thus, IPPs fail to allege injury under 24 state antitrust laws, 20 state consumer protection laws, and 35 state unjust enrichment laws. Generic Br. at 31-35.

2. IPPs Lack Standing Where They Are Barred From Bringing Claims

IPPs assert claims under the antitrust laws of several states which expressly follow *Illinois Brick* or otherwise bar indirect purchasers from asserting damages claims under antitrust laws: Massachusetts, Puerto Rico, Rhode Island, Illinois, and Utah.[44] Where plaintiffs, like IPPs, assert antitrust claims under the laws of states which do not allow indirect purchasers standing for damages claims, dismissal is proper. *See, e.g.*, *In re Terazosin Hydrochloride Antitrust Litig.*, 160 F. Supp. 2d 1365, 1372 (S.D. Fla. 2001); Generic Br. at 44-47.

3. IPPs May Not Circumvent *Illinois Brick* by Asserting Antitrust Claims Under Consumer Protection and Unjust Enrichment Theories of 21 States

IPPs have further attempted to circumvent *Illinois Brick* by recasting their antitrust claims as consumer protection or unjust enrichment claims. Courts routinely reject this circumvention attempt. *See In re DDAVP Indirect Purchaser Antitrust Litig.*, 903 F. Supp. 2d 198, 232 (S.D.N.Y. 2012) ("a plaintiff cannot circumvent the statutory framework by recasting an antitrust claim as one for unjust enrichment") (citing *In re K-Dur Antitrust Litig.*, No. 01-1652, 2008 WL 2660780, at *5 (D.N.J. Feb. 28, 2008)). Thus, IPPs' consumer protection and unjust enrichment claims under the laws of 19 states that apply *Illinois Brick* must fail.[45] *See* Generic Br. at 33-36.

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[43] IPPs allege no violations of Georgia or Pennsylvania law.

[44] *See* IPP ¶¶ 201.i., 201.t., 201.w., 201.aa, 207.e., 207.i., 207.t, 207.u., 207.x. *See* Generic Br. at 45 n.24.

[45] Alabama, Alaska, Colorado, Connecticut, Delaware, Illinois, Idaho, Massachusetts, Missouri, Montana, New Jersey, New York, Oklahoma, Puerto Rico, Rhode Island, South Carolina, Utah, Virginia, and Washington. *See* Generic Br. at 31, 35 n.14; Appendix 2.

B. IPPs Cannot State A Monopolization Claim Under The Laws Of Kansas, New York Or Tennessee

IPPs allege monopolization claims under the laws of Kansas, New York and Tennessee. *See* IPP ¶ 207.g, 207.p, 207.w. However, to state a claim under these state laws, IPPs are required to plead some sort of concerted action. Unilateral conduct such as monopolization is insufficient. *See* Kan. Stat. Ann. § 50-132; *In re Relafen Antitrust Litig.*, 221 F.R.D. 260, 283 (D. Mass. 2004) (Kansas statute "prohibits combinations and conspiracies only"); N.Y. Gen. Bus. Law § 340(1); *Commonwealth Elec. Inspection Servs., Inc. v. Town of Clarence*, 6 A.D.3d 1185, 1186 (4th Dep't 2004); Tenn. Code Ann. §§ 47-25-101 to 112; *In re Ditropan XL Antitrust Litig.*, 529 F. Supp. 2d 1098, 1108-09 (N.D. Cal. 2007). Thus, IPPs monopolization claims, including any claims related to Forest's alleged hard switch, must fail in these states.

C. IPPs' Consumer Protection Claims Must Be Dismissed

1. IPPs' Undifferentiated Claims Under the Consumer Protection Laws of 25 States Do Not Suffice to Survive Dismissal

IPPs' consumer protection claims under the laws of 25 states in Count III of their Complaint are entirely undifferentiated and flagrantly fail to meet IPPs' pleading burden.[46] *See In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 255 (D. Conn. 2015) (dismissing plaintiffs' undifferentiated consumer protection and unjust enrichment claims as they "attempt[ed] to build a Frankensteinian equivalent of *Actavis* to reach the very same conduct . . . by stitching together a hodge-podge of state-law claims"). For instance, some consumer protection laws require a showing of consumer deception,[47] while others require a consumer transaction or conduct that is

[46] *See* IPP ¶ 215; Appendix 3; *see also* Generic Br. at 37-42.

[47] Arizona (Ariz. Rev. Stat. § 44-1522); California (Cal. Bus. & Prof. Code § 172004); District of Columbia (D.C. Code § 28-3904); Idaho (Idaho Code § 48-603); Illinois (815 Ill. Comp. Stat. 505/10a(a)); Kansas (Kan. Stat. Ann. § 50-626); Maine (Me. Stat. tit. 5, §§ 207, 213(1)); Michigan (Mich. Comp. Laws § 445.903); Nevada (Nev. Rev. Stat. §§ 41.600, *et seq.*,

consumer-oriented.[48] Some consumer protection statutes are inapplicable to antitrust conduct,[49] or require conduct that is primarily intrastate.[50] Others only allow suits by consumers who are natural persons with regards to transactions made primarily for *personal* or *household* purposes,[51] while another only permits elderly or disabled persons to bring a private action.[52] Still others prohibit class actions or indirect purchaser actions altogether.[53] IPPs again use the same copy-and-paste approach to pleading, in providing one large list of statute titles, failing to meet their pleading burden under Rule 8(a), *Twombly*, and *Iqbal*. Dismissal is the only proper remedy of these claims. *See Aggrenox*, 94 F. Supp. 3d at 255. *See also* Generic Br. at 37-42;

598.0915); New Mexico (N.M. Stat. Ann. § 57-12-2(D)); New York (N.Y. Gen. Bus. Law § 349); Rhode Island (*George v. George F. Berkander, Inc.*, 169 A.2d 370, 371 (R.I. 1961)); Tennessee (Tenn. Code Ann. § 47–18–104); Utah (Utah Code Ann. §§ 13-11-2, -5); West Virginia (W. Va. Code §§ 46A-6-104, -102(7)).

[48] *Sheet Metal Workers*, 737 F. Supp. 2d at 411, 413, 417-18 (Arizona, Michigan, Idaho, New York); Kansas (Kan. Stat. Ann. §§ 50-626, -627); Missouri (Mo. Rev. Stat. § 407.020(1)); New Mexico (N.M. Stat. Ann. §§ 57-12-3, -12-2 (2006)); West Virginia (W. Va. Code §§ 46A-6-104, -102(7)); District of Columbia (D.C. Code § 28-3905(k)); Illinois (815 Ill. Comp. Stat. 505/10a(a)); Nebraska (Neb. Rev. Stat. §§ 59-1601).

[49] Illinois (815 Ill. Comp. Stat. 505/2); Kansas (Kan. Stat. Ann. §§ 50-626(a), 627(a)); New Mexico N.M. Stat Ann. § 57-12-2(D); Tennessee (Tenn. Code Ann. § 47-18-104(b)); Utah (Utah Code Ann. § 13-11-4); District of Columbia (D.C. Code § 28-3904); Idaho (Idaho Code Ann. § 48-603); Michigan (Mich. Comp. Laws § 445.903); Rhode Island (R.I. Gen. Laws § 6–13.1–1(6)(i)-(xx)); West Virginia (W. Va. Code § 46A-6-102(7)); *see* Generic Br.at 40.

[50] Florida (*Coastal Physician Servs. of Broward Cnty. v. Ortiz*, 764 So. 2d 7, 8 (Fla. Dist. Ct. App. 1999)); Massachusetts (Mass. Gen. Laws ch. 93A, § 1); New Hampshire (N.H. Rev. Stat. Ann. § 358-A:2); New York (N.Y. Gen. Bus. Law § 349(a)); North Carolina (N.C. Gen. Stat. § 75-1.1); California (*Meridian Project Sys., Inc. v. Hardin Const. Co., LLC*, 404 F. Supp. 2d 1214, 1225 (E.D. Cal. 2005)); *see* Generic Br. at 40-41.

[51] Hawaii (Haw. Rev. Stat. § 480-2(d)); Kansas (Kan. Stat. Ann. § 50-624, -634); Maine (Me. Stat. tit. 5, § 213(1)); Montana (Mont. Code Ann. §§ 30-14-102, -133); North Carolina (N.C. Gen. Stat. § 75-1.1); Rhode Island (R.I. Gen. Laws § 6-13.1-5.2); Utah (Utah Code Ann. §§ 13-11-3(2)(a); 13-11-19); Vermont (Vt. Stat. Ann. tit. 9 § 2461(b)).

[52] Nevada (Nev. Rev. Stat. § 598.0977); *see* Generic Br. at 40.

[53] Kansas (Kan. Stat. Ann. § 50-634(b)); Montana (Mont. Code Ann. § 30-14-133(1)); Tennessee (Tenn. Code Ann. §§ 47-18-109(g)); Utah (Utah Code Ann. § 13-11-19(2)); Illinois (740 Ill. Comp. Stat. § 10/7(2)); Massachusetts (Mass. Gen. Laws. ch. 93A, § 11); *see* Generic Br. at 40.

Appendix 3.

D. IPPs' Unjust Enrichment Claims Fail

1. IPPs Must Plead Their Unjust Enrichment Claims Under Specific Laws And May Not Simply List The Laws of 44 States in One Catchall Claim

As they do with their consumer protection claims, IPPs provide a laundry list of 44 states in one omnibus unjust enrichment claim. *See* IPP ¶ 226. Such undifferentiated unjust enrichment claims are routinely dismissed. *See, e.g.*, *Wellbutrin XL*, 260 F.R.D. at 167; *In re Ductile Iron Pipe Fittings Indirect Purchaser Antitrust Litig.*, No. 12-169, 2013 WL 5503308, at *8 (D.N.J. Oct. 2, 2013); *In re Refrigerant Compressors Antitrust Litig.*, No. 2:09-md-02042, 2013 WL 1431756, at *23-25 (E.D. Mich. Apr. 9, 2013). This vague pleading is impermissible under the Federal Rules. *See Iqbal*, 556 U.S. at 678 ("[N]aked assertion[s]," "[t]hreadbare recitals of the elements of a cause of action," and "mere conclusory statements" are insufficient to survive dismissal). Accordingly, IPPs' unjust enrichment claim in Count IV of their Complaint fails. *See also* Generic Br. at 42-44.

2. Unjust Enrichment is not a Means to Avoid the Requirements of IPPs' Antitrust and Consumer Protection Claims

To the extent recognized, unjust enrichment is an equitable claim that exists only to fill gaps in the law where no express remedy at law exists. *See Walters v. MedSouth Record Mgmt., LLC*, 38 So. 3d 245, 246 (La. 2010) ("The unjust enrichment remedy is 'only applicable to fill a gap in the law where no express remedy is provided.'"). It is not, as IPPs would have it, an alternative legal regime designed to allow the plaintiff to evade the requirements or limits of pre-existing state laws. *See Fed. Treasury Enter. Sojuzplodoimport v. Spirits Int'l N.V.*, 400 F. App'x 611, 613-14 (2d Cir. 2010).

IPPs bring unjust enrichment claims with respect to states for which IPPs assert no claims

other than unjust enrichment,[54] or in states where no independent cause of action for unjust enrichment exists.[55] These claims must be dismissed. *See Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, plc*, 737 F. Supp. 2d 380, 426 (E.D. Pa. 2010) (unjust enrichment claims dismissed for states where "plaintiffs *do not assert* any antitrust or consumer protection claims"). *See* Generic Br. at 42-48.

Lastly, because unjust enrichment is a quasi-contract theory, many states require specific relationships between the quasi-contractual parties. IPPs fail to allege facts suggesting that they have met these requirements in those states, which fall into two categories: (1) those states that require privity between the quasi-contractual parties (or something approaching privity)[56] and (2) those states that require that the quasi-contractual benefit provided to the defendant be direct, rather than indirect.[57] *See* Appendix 4; Generic Br. at 44-48. These unjust enrichment claims

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[54] Alaska, Arkansas, Colorado, Connecticut, Delaware, New Jersey, Oklahoma, South Carolina, Washington, and Wyoming. *See* Generic Br. at 44-47.

[55] California (*See IB Melchior v. New Line Prods., Inc.*, 106 Cal. App. 4th 779, 793 (Cal. Ct. App. 2003)); Illinois (*Sheet Metal Workers*, 737 F. Supp. 2d at 432-33, 435); Mississippi (*Cole v. Chevron USA, Inc.*, 554 F. Supp. 2d 655, 671, 674 (S.D. Miss. 2007)). *See* Generic Br. at 44.

[56] Idaho (*Beco Constr. Co. v. Bannock Paving Co., Inc.*, 797 P.2d 863, 865-67 (Idaho 1990)); Illinois (*Martis v. Grinnell Mut. Reinsurance Co.*, 905 N.E.2d 920, 928 (Ill. App. Ct. 2009)); Kansas (*Haz-Mat Response, Inc. v. Certified Waste Servs. Ltd.*, 910 P.2d 839, 846-47 (Kan. 1996)); New York (*Reading Int'l, Inc. v. Oaktree Capital Mgmt. LLC*, 317 F. Supp. 2d 301, 333-34 (S.D.N.Y. 2003)); South Carolina (*Pitts v. Jackson Nat'l Life Ins. Co.*, 574 S.E.2d 502, 511-12 (S.C. Ct. App. 2002)).

[57] Alabama (*Danny Lynn Elec. & Plumbing, LLC v. Veolia ES Solid Waste Se., Inc.*, No. 2:09-cv-192, 2011 WL 2893629, at *6 (M.D. Ala. July 19, 2011)); Arizona, District of Columbia, Florida, Kansas, Maine, Massachusetts, Michigan, New York, Rhode Island, West Virginia, Wisconsin (*Refrigerant Compressors*, 2013 WL 1431756, at *25-26); Idaho (*Sheet Metal Workers*, 737 F. Supp. 2d at 433 n.26); New Jersey (*Fasching v. Kallinger*, 510 A.2d 694, 699-700 (N.J. Super. Ct. App. Div. 1986)); North Carolina (*Effler v. Pyles*, 380 S.E.2d 149, 152 (N.C. Ct. App. 1989)); North Dakota (*Ritter, Laber & Assocs., Inc. v. Koch Oil, Inc.*, 680 N.W.2d 634, 642-43 (N.D. 2004)); South Carolina (*Myrtle Beach Hosp., Inc. v. City of Myrtle Beach*, 532 S.E.2d 868, 872-73 (S.C. 2000)); Utah (*Concrete Prods. Co. v. Salt Lake Co.*, 734 P.2d 910, 911-12 (Utah 1987)); Washington (*Keil v. Scholten*, No. 48051-1-I, 2002 WL

fail.

* * *

The failure of IPPs to state a claim under any of these states' antitrust, consumer protection and unjust enrichment laws further exposes IPPs' allegations for what they are—evasion tactics purposed on the circumvention of the Supreme Court's prohibition on end-payor antitrust recovery in *Illinois Brick*. This court should dismiss them in their entirety.

CONCLUSION

For the foregoing reasons, Plaintiffs' claims should be dismissed with prejudice.

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988562, at *5 (Wash. Ct. App. Feb. 4, 2002)); Wyoming (*Boyce v. Freeman*, 39 P.3d 1062, 1065-66 (Wyo. 2002)).

Appendix 1:
State Law Claims Asserted By Indirect Purchaser Plaintiffs

State Antitrust Claims (Counts 1-2)	State Unfair Competition and Consumer Protection Claims (Count 3)	State Unjust Enrichment Claims (Count 4)	
1. Arizona	1. Alabama	1. Alabama	23. Nebraska
2. California	2. Arizona	2. Alaska	24. Nevada
3. D.C.	3. California	3. Arizona	25. New Hampshire
4. Florida	4. D.C.	4. Arkansas	26. New Jersey
5. Hawaii	5. Florida	5. California	27. New Mexico
6. Illinois	6. Hawaii	6. Colorado	28. New York
7. Iowa	7. Idaho	7. Connecticut	29. North Carolina
8. Kansas	8. Illinois	8. Delaware	30. North Dakota
9. Maine	9. Kansas	9. D.C.	31. Oklahoma
10. Massachusetts	10. Maine	10. Florida	32. Oregon
11. Michigan	11. Massachusetts	11. Hawaii	33. Rhode Island
12. Minnesota	12. Michigan	12. Idaho	34. South Carolina
13. Mississippi	13. Missouri	13. Illinois	35. South Dakota
14. Nebraska	14. Montana	14. Iowa	36. Tennessee
15. Nevada	15. Nebraska	15. Kansas	37. Utah
16. New Hampshire	16. Nevada	16. Maine	38. Vermont
17. New Mexico	17. New Hampshire	17. Massachusetts	39. Virginia
18. New York	18. New Mexico	18. Michigan	40. Washington
19. North Carolina	19. New York	19. Minnesota	41. West Virginia
20. North Dakota	20. North Carolina	20. Mississippi	42. Wisconsin
21. Oregon	21. Rhode Island	21. Missouri	43. Wyoming
22. Puerto Rico	22. Tennessee	22. Montana	44. Puerto Rico
23. Rhode Island	23. Utah		
24. South Dakota	24. Vermont		
25. Tennessee	25. West Virginia		
26. Utah			
27. Vermont			
28. West Virginia			
29. Wisconsin			

Appendix 2:
Bases to Dismiss IPPs' State Antitrust Law Count II

State	Statute of Limitations (Years)	Failure to Allege Antitrust Injury	Failure to Allege Large Unjustified Reverse Payment	Lacks Article III Standing – No Purchases	Lacks Standing Where Barred from Bringing Claims	Concerted Action Required
Arizona	4	X	X	X		
California	4	X	X			
District of Columbia	4	X	X	X		
Florida	4	X	X			
Hawaii	4	X	X	X		
Illinois	4	X	X	X	X	
Iowa	4	X	X	X		
Kansas	3	X	X			X
Maine		X	X	X		
Massachusetts	4	X	X	X	X	
Michigan	4	X	X	X		
Minnesota	4	X	X	X		
Mississippi	3	X	X	X		
Nebraska	4	X	X	X		
Nevada	4	X	X			
New Hampshire	4	X	X	X		
New Mexico	4	X	X	X		
New York	4	X	X			X
North Carolina	4	X	X	X		
North Dakota	4	X	X	X		
Oregon	4	X	X	X		
Puerto Rico	4	X	X	X	X	
Rhode Island	4	X	X	X	Not Retroactive	
South Dakota	4	X	X	X		
Tennessee	3	X	X	X		X
Utah	4	X	X	X	X	
Vermont		X	X	X		
West Virginia	4	X	X	X		
Wisconsin		X	X	X		
Total:	**26**	**29**	**29**	**24**	**5**	**3**

Appendix 3:
Bases to Dismiss IPPs' Consumer Protection Law Count III

State	Statute of Limitations (Years)	Lacks Article III Standing – No Purchases	Consumer Deception Required	Consumer Oriented or Consumer Nexus Required	Inapplicable to Antitrust Conduct	Allows Suits Only in Consumer Capacity	Additional Reasons to Dismiss
Alabama	1	X					
Arizona	1	X	X	X			
California	4		X				Intrastate Conduct Required
District of Columbia	4	X	X	X	X		
Florida	4						Intrastate Conduct Required; No Class Action
Hawaii	4	X				X	
Idaho	2	X	X	X	X		
Illinois	3	X	X	X	X		No Class Action
Kansas	3		X	X	X	X	No Class Action
Maine		X	X			X	
Massachusetts	4	X					Intrastate Conduct Required; Indirect Purchasers Barred
Michigan		X	X	X	X		
Missouri	5	X		X			
Montana	2	X				X	No Class Action
Nebraska	4	X		X			
Nevada	4		X				Only Elderly/ Disabled Can Bring Action
New Hampshire	3	X					Intrastate Conduct Required
New Mexico	4	X	X	X	X		
New York	3		X	X			Intrastate Conduct Required
North Carolina	4	X				X	Intrastate Conduct Required
Rhode Island		X	X		X	X	
Tennessee	1	X	X		X		No Class Action
Utah	4	X	X		X	X	No Class Action
Vermont		X				X	
West Virginia	4	X	X	X	X		
Total:	**21**	**20**	**15**	**11**	**10**	**8**	**12**

Appendix 4:
IPPs' Unjust Enrichment Law Count IV

State	Statute of Limitations (Years)	Lacks Article III Standing – No Purchases	No Effort to Plead Elements of Claim	End Run around *Illinois Brick*	No Unjust Enrichment in States with No Other Claims	Privity with Defendant Required	Direct Benefit Required	No Independent Cause of Action
Alabama		X	X	X			X	
Alaska	3	X	X	X	X			
Arizona	4	X	X				X	
Arkansas	3	X	X		X			
California	4		X					X
Colorado	3	X	X	X	X			
Connecticut		X	X	X	X			
Delaware	3		X	X	X			
District of Columbia	4	X	X				X	
Florida	4		X				X	
Hawaii		X	X					
Idaho	4	X	X	X		X		
Illinois	5	X	X			X		X
Iowa	5	X	X					
Kansas	3		X			X	X	
Maine		X	X				X	
Massachusetts		X	X	X			X	
Michigan		X	X				X	
Minnesota		X	X	X				
Mississippi	3	X	X					X
Missouri	5	X	X	X				
Montana	3	X	X	X				
Nebraska	4	X	X					
Nevada	4		X					
New Hampshire	3	X	X					
New Jersey			X	X	X		X	
New Mexico	4	X	X					
New York			X	X		X	X	
North Carolina	3	X	X				X	

State	Statute of Limitations (Years)	Lacks Article III Standing – No Purchases	No Effort to Plead Elements of Claim	End Run around *Illinois Brick*	No Unjust Enrichment in States with No Other Claims	Privity with Defendant Required	Direct Benefit Required	No Independent Cause of Action
North Dakota	4	X	X				X	
Oklahoma	2	X	X	X	X			
Oregon		X	X					
Puerto Rico		X	X	X				
Rhode Island		X	X	X			X	
South Carolina	3		X	X	X	X	X	
South Dakota		X	X	X				
Tennessee	3	X	X					
Utah	4	X	X	X			X	
Vermont		X	X					
Virginia	3		X	X	X			
Washington	3	X	X	X	X		X	
West Virginia		X	X				X	
Wisconsin		X	X				X	
Wyoming	4	X	X		X		X	
Total:	**28**	**35**	**44**	**20**	**11**	**5**	**19**	**3**